

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL PRESCRIPTION) No. 17-md-2804
5 OPIATE LITIGATION NO. 2804)
6)
7 APPLIES TO ALL CASES) Hon. Dan A. Polster
8)

9 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
10 CONFIDENTIALITY REVIEW

11 VIDEO DEPOSITION OF JOHN GILLIES

12 February 7, 2019

13 9:07 a.m.

14 HIGHLY CONFIDENTIAL
15 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

16 Reporter: John Arndt, CSR, CCR, RDR, CRR
17 CSR No. 084-004605
18 CCR No. 1186

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<p>1 DEPOSITION OF JOHN GILLIES produced, 2 sworn, and examined on January 7, 2019, at Bryan Cave 3 Leighton Paisner LLP, 211 North Broadway, Suite 3600, 4 in the City of St. Louis, State of Missouri, before 5 John Arndt, a Certified Shorthand Reporter and 6 Certified Court Reporter.</p>	<p>1 INDEX OF INTERROGATION 2 Examination by Mr. Ko Page 9 3 Examination by Ms. Herzfeld Page 274 4 Examination by Mr. O'Connor Page 326</p>
<p>5 APPEARANCES OF COUNSEL</p>	<p>5 INDEX OF EXHIBITS</p>
<p>6 On Behalf of Plaintiffs: 7 Keller Rohrback LLP 8 1201 Third Avenue, Suite 3200 9 Seattle, WA 98101 10 (206) 623-1900 11 BY: MR. DAVID J. KO 12 dko@kellerrohrback.com 13 MS. ALISON S. GAFFNEY 14 agaffney@kellerrohrback.com 15 MR. DEAN KAWAMOTO 16 dkawamoto@kellerrohrback.com</p>	<p>6 Exhibit Mallinckrodt-Gillies-001 Page 12 7 (Notice of deposition)</p>
<p>13 On Behalf of Tennessee Action: 14 Branstetter, Stranch & Jennings, PLLC 15 223 Rosa L. Parks Avenue, Suite 200 16 Nashville, TN 37203 17 (615) 254-8801 18 BY: MS. TRICIA HERZFELD 19 triciah@bsjfirm.com</p>	<p>8 Exhibit Mallinckrodt-Gillies-002 Page 52 9 (E-mail chain with attachment) 10 (MNK-T1_0000273575 - MNK-T1_0000273582)</p>
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<p>21 On Behalf of Walmart: 22 Jones Day 23 325 John H. McConnell Boulevard, Suite 600 24 Columbus, OH 43215 (614) 469-3939 BY: MS. BRANDY H. RANJAN branjah@jonesday.com</p>	<p>14 Exhibit Mallinckrodt-Gillies-004 Page 80 15 (E-mail message) 16 (MNK-T1_0001806623)</p>
<p>Page 3</p>	<p>14 Exhibit Mallinckrodt-Gillies-005 Page 80 15 (Dosage Suspicious Orders for Dec 2003) 16 (MNK-T1_0001806624)</p>
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<p>2 On Behalf of Endo Pharmaceuticals and Par 3 Pharmaceuticals: 4 Arnold & Porter Kaye Scholer, LLP 5 70 West Madison Street, Suite 4200 6 Chicago, IL 60602 7 (312) 583-2434 8 BY: MS. CAITLIN M. MIKA 9 caitlin.mika@arnoldporter.com 10 (present via speakerphone)</p>	<p>17 Exhibit Mallinckrodt-Gillies-007 Page 98 18 (Suspicious Order Monitoring 19 Team Charter) 20 (MNK-T1_0000496062)</p>
<p>11 On Behalf of Cardinal Health: 12 Armstrong Teasdale, LLP 13 7700 Forsyth Boulevard, Suite 1800 14 St. Louis, MO 63105 15 (314) 552-6672 16 BY: MS. SARAH E. HARMON 17 sharmon@armstrongteasdale.com</p>	<p>21 Exhibit Mallinckrodt-Gillies-008 Page 105 22 (Notes from meeting with DEA Albany) 23 (MNK-T1_0007053963 - MNK-T1_0007053966)</p>
<p>12 On Behalf of Mallinckrodt, SpecGX LLC, and John 13 Gillies: 14 Ropes & Gray LLP 15 800 Boylston Street 16 Boston, MA 02199 17 (617) 951-7000 18 BY: MR. ANDREW O'CONNOR 19 andrew.o'connor@ropesgray.com 20 MR. JOSH GOLDSTEIN 21 joshua.goldstein@ropesgray.com</p>	<p>22 Exhibit Mallinckrodt-Gillies-009 Page 132 23 (DEA Compliance Procedure) 24 (MNK-T1_0000419993 - MNK-T1_0000419997)</p>
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<p>2 On Behalf of Endo Pharmaceuticals and Par 3 Pharmaceuticals: 4 Arnold & Porter Kaye Scholer, LLP 5 70 West Madison Street, Suite 4200 6 Chicago, IL 60602 7 (312) 583-2434 8 BY: MS. CAITLIN M. MIKA 9 caitlin.mika@arnoldporter.com 10 (present via speakerphone)</p>	<p>2 Exhibit Mallinckrodt-Gillies-010 Page 118 3 (E-mail message with attachment) 4 (MNK-T1_0000273892 - MNK-T1_0000273895)</p>
<p>11 On Behalf of Cardinal Health: 12 Armstrong Teasdale, LLP 13 7700 Forsyth Boulevard, Suite 1800 14 St. Louis, MO 63105 15 (314) 552-6672 16 BY: MS. SARAH E. HARMON 17 sharmon@armstrongteasdale.com</p>	<p>5 Exhibit Mallinckrodt-Gillies-011 Page 144 6 (DEA Compliance Procedure) 7 (MNK-T1_0000296382 - MNK-T1_0000296386)</p>
<p>12 On Behalf of Mallinckrodt, SpecGX LLC, and John 13 Gillies: 14 Ropes & Gray LLP 15 800 Boylston Street 16 Boston, MA 02199 17 (617) 951-7000 18 BY: MR. ANDREW O'CONNOR 19 andrew.o'connor@ropesgray.com 20 MR. JOSH GOLDSTEIN 21 joshua.goldstein@ropesgray.com</p>	<p>8 Exhibit Mallinckrodt-Gillies-012 Page 152 9 (Global Controlled Substance 10 Compliance Procedure) 11 (MNK-T1_0004154292 - MNK-T1_0004154296)</p>
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<p>2 On Behalf of Endo Pharmaceuticals and Par 3 Pharmaceuticals: 4 Arnold & Porter Kaye Scholer, LLP 5 70 West Madison Street, Suite 4200 6 Chicago, IL 60602 7 (312) 583-2434 8 BY: MS. CAITLIN M. MIKA 9 caitlin.mika@arnoldporter.com 10 (present via speakerphone)</p>	<p>14 Exhibit Mallinckrodt-Gillies-015 Page 169 15 (11/02/10 memorandum) 16 (MNK-T1_0000269399 - MNK-T1_0000269400)</p>
<p>11 On Behalf of Cardinal Health: 12 Armstrong Teasdale, LLP 13 7700 Forsyth Boulevard, Suite 1800 14 St. Louis, MO 63105 15 (314) 552-6672 16 BY: MS. SARAH E. HARMON 17 sharmon@armstrongteasdale.com</p>	<p>16 Exhibit Mallinckrodt-Gillies-016 Page 172 17 (Global Controlled Substance 18 Compliance Procedure) 19 (MNK-T1_0000264275 - MNK-T1_0000264278)</p>
<p>12 On Behalf of Mallinckrodt, SpecGX LLC, and John 13 Gillies: 14 Ropes & Gray LLP 15 800 Boylston Street 16 Boston, MA 02199 17 (617) 951-7000 18 BY: MR. ANDREW O'CONNOR 19 andrew.o'connor@ropesgray.com 20 MR. JOSH GOLDSTEIN 21 joshua.goldstein@ropesgray.com</p>	<p>18 Exhibit Mallinckrodt-Gillies-017 Page 173 19 (E-mail chain with attachment) 20 (MNK-T1_0000264199 - MNK-T1_0000264204)</p>
<p>18 Also present: James Arndt, videographer 19 20 21 22 23 24</p>	<p>20 Exhibit Mallinckrodt-Gillies-018 Page 179 21 (Mallinckrodt Suspicious Order 22 Monitoring Procedure) 23 (MNK-T1_0000259166 - MNK-T1_0000259170)</p>
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<p>1 INDEX OF EXHIBITS (CONTINUED)</p> <p>2</p> <p>3 Exhibit Mallinckrodt-Gillies-028 Page 260</p> <p>4 (Draft Notes for SOM Steering</p> <p>5 Committee Meeting 09/28/11)</p> <p>6 (MNK-T1_0002077756 - MNK-T1_0002077758)</p> <p>7 Exhibit Mallinckrodt-Gillies-029 Page 262</p> <p>8 (E-mail message)</p> <p>9 (MNK-T1_0000284620)</p> <p>10 Exhibit Mallinckrodt-Gillies-030 Page 269</p> <p>11 (Letter to Assistant U.S. Attorney)</p> <p>12 (MNK-T1_0008434954 - MNK-T1_0008434992)</p> <p>13 Exhibit Mallinckrodt-Gillies-031 Page 302</p> <p>14 (List of files on server)</p> <p>15 (MNK-T1_0007900223)</p> <p>16 Exhibit Mallinckrodt-Gillies-032 Page 305</p> <p>17 (Prescription Drug Prosecutions)</p> <p>18 (MNK-TNSTA00607255 - MNK-TNSTA00607313)</p> <p>19</p> <p>20 (Exhibits are attached.)</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 Gray, on behalf of the witness, Mallinckrodt LLC, and</p> <p>2 SpecGX LLC.</p> <p>3 MR. O'CONNOR: Andrew O'Connor on behalf</p> <p>4 of the witness, Mallinckrodt LLC, and SpecGX.</p> <p>5 THE VIDEOGRAPHER: Will attorneys present</p> <p>6 by phone please identify themselves?</p> <p>7 MS. MIKA: Caitlin Mika from Arnold &</p> <p>8 Porter on behalf of Endo and Par entities.</p> <p>9 MS. RUSSO: Shana Russo, Reed Smith, on</p> <p>10 behalf of AmerisourceBergen Drug Corporation.</p> <p>11 THE VIDEOGRAPHER: The court reporter is</p> <p>12 John Arndt and he will now swear in the witness.</p> <p>13</p> <p>14 The witness, JOHN GILLIES, first having been</p> <p>15 duly sworn, testified as follows:</p> <p>16 EXAMINATION</p> <p>17 BY MR. KO:</p> <p>18 Q. Good morning.</p> <p>19 A. Good morning.</p> <p>20 Q. Would you please state and spell your name</p> <p>21 for the record?</p> <p>22 A. Sure. John Gillies. G-I-L-L-I-E-S.</p> <p>23 Q. And Mr. Gillies, where do you currently</p> <p>24 reside?</p>

<p style="text-align: right;">Page 10</p> <p>1 A. In St. Louis, Missouri.</p> <p>2 Q. And have you had your deposition taken</p> <p>3 before?</p> <p>4 A. Yes.</p> <p>5 Q. Approximately how many times?</p> <p>6 A. Twice.</p> <p>7 Q. And was that in connection with your time</p> <p>8 at FBI or in connection with your time at Mallinckrodt?</p> <p>9 A. With my previous employer.</p> <p>10 Q. Not Mallinckrodt?</p> <p>11 A. Not Mallinckrodt.</p> <p>12 Q. So you understand generally how these</p> <p>13 depositions go, but just as a brief reminder of the</p> <p>14 important rules to me, it's very important that we</p> <p>15 create a clean record.</p> <p>16 As we alluded to before, the court</p> <p>17 reporter has the most important job here, so it's</p> <p>18 important not to speak over one another, so please wait</p> <p>19 until I finish my question before moving on to your</p> <p>20 response, and likewise I'll wait until you finish your</p> <p>21 response before moving onto my next question.</p> <p>22 Okay?</p> <p>23 A. Yes.</p> <p>24 Q. It's also very important that to the</p>	<p style="text-align: right;">Page 12</p> <p>1 Is that your understanding?</p> <p>2 A. Yes.</p> <p>3 Q. I'm going to go ahead and hand you a copy</p> <p>4 of what's going to be marked as Gillies Exhibit 1.</p> <p>5 [Exhibit Mallinckrodt-Gillies-001</p> <p>6 marked for identification.]</p> <p>7 Q. And I'll represent for the record that</p> <p>8 this is the amended notice of deposition pursuant to</p> <p>9 Rule 30(b)6 that we issued to Mallinckrodt.</p> <p>10 Does that look familiar to you, Mr.</p> <p>11 Gillies?</p> <p>12 A. Yes.</p> <p>13 Q. And just so I understand it, just so the</p> <p>14 record is clear, you are here testifying on behalf of</p> <p>15 Mallinckrodt; is that correct?</p> <p>16 A. Correct.</p> <p>17 Q. And Mallinckrodt is defined as</p> <p>18 Mallinckrodt LLC and SpecGX LLC; is that correct?</p> <p>19 A. Yes.</p> <p>20 Q. And are you also testifying on behalf of</p> <p>21 Mallinckrodt PLC today?</p> <p>22 A. No, not that I'm aware of.</p> <p>23 MR. KO: And I'll note for the record, as</p> <p>24 counsel is aware, that Mallinckrodt PLC has moved to</p>
<p style="text-align: right;">Page 11</p> <p>1 extent that I ask a yes-or-no question and your answer</p> <p>2 is in fact yes or no, please say those words rather</p> <p>3 than shaking your head or nodding your head.</p> <p>4 Sound good?</p> <p>5 A. Yes.</p> <p>6 Q. And from time to time, counsel, your</p> <p>7 counsel, or other counsel might object to my</p> <p>8 questioning, but unless you get a clear instruction not</p> <p>9 to answer, I'd ask that you respond to my question.</p> <p>10 Does that sound good?</p> <p>11 A. Yes. Yes.</p> <p>12 Q. And Mr. Gillies, we'll be here for a</p> <p>13 substantial period of time today, so to the extent you</p> <p>14 need breaks, please ask and we'll do our best to</p> <p>15 accommodate.</p> <p>16 Okay?</p> <p>17 A. Thank you.</p> <p>18 Q. Mr. Gillies, is there anything that you</p> <p>19 can think of today that would prevent you from</p> <p>20 testifying truthfully or honestly?</p> <p>21 A. No.</p> <p>22 Q. Great. I understand that you have been</p> <p>23 designated on behalf of Mallinckrodt to testify on</p> <p>24 certain topics pursuant to a 30(b)6 notice.</p>	<p style="text-align: right;">Page 13</p> <p>1 dismiss themselves from this litigation, but it is</p> <p>2 certainly plaintiffs' position that the PLC should be</p> <p>3 in the litigation, and we expect this testimony to be</p> <p>4 on behalf of the PLC as well.</p> <p>5 MR. O'CONNOR: Okay. And we want to make</p> <p>6 clear that his testimony today is only on behalf of LLC</p> <p>7 and SpecGX LLC, and PLC is not subject to the</p> <p>8 jurisdiction of the Northern District of Ohio.</p> <p>9 BY MR. KO:</p> <p>10 Q. Now, throughout this day -- we'll be</p> <p>11 taking a look at that notice shortly, but throughout</p> <p>12 this day we'll also be looking potentially at some</p> <p>13 documents that include Covidien e-mail addresses and</p> <p>14 Covidien labels.</p> <p>15 Can we agree for purposes of the</p> <p>16 deposition today that Mallinckrodt includes Covidien?</p> <p>17 A. Yes.</p> <p>18 Q. And the same with Tyco. There will be</p> <p>19 some -- perhaps some Tyco e-mail addresses and some</p> <p>20 Tyco documents.</p> <p>21 Can we agree that Tyco is synonymous with</p> <p>22 Mallinckrodt for purposes of today's deposition?</p> <p>23 MR. O'CONNOR: I just want to be very</p> <p>24 clear that those are other companies, and he's</p>

<p style="text-align: right;">Page 14</p> <p>1 authorized to speak, as he said, on behalf of LLC and 2 SpecGX. 3 MR. KO: When I refer -- I understand, 4 Andrew. 5 BY MR. KO: 6 Q. When I refer to Tyco and/or Covidien and 7 some documents, unless there is a clear objection or a 8 clear instruction otherwise, can we agree that just for 9 ease of reference that when I refer to Tyco and/or 10 Covidien it's also synonymous with Mallinckrodt? 11 A. Yes. 12 Q. Okay, great. Turning to this deposition 13 notice. As we discussed before, there are some topics 14 that you have been designated to testify on behalf of 15 Mallinckrodt, and that includes, if you turn to Page 5, 16 Topic 1. Is that correct? 17 A. Yes. 18 Q. And I also understand that you have been 19 designated by Mallinckrodt to testify as to portions of 20 Topic 2. Is that correct? 21 A. Yes. 22 Q. And in particular I think there are some 23 carve-outs there, so I believe that your testimony 24 today is specifically regarding suspicious order</p>	<p style="text-align: right;">Page 16</p> <p>1 sent to you by the DEA and any other communications 2 between you and the DEA regarding your marketing of 3 your opioid products, your response to these letters, 4 all subsequent actions you took in response to those 5 communications, and all budgets for any such actions by 6 year, end quote. 7 Is that a correct understanding of what 8 you're testifying on behalf of? 9 A. Yes. 10 Q. Great. Now, I also understand that you 11 are testifying on behalf of Mallinckrodt for portions 12 of Topic 4. Is that correct? 13 A. Yes. 14 Q. And again, so the record is clear, the 15 portion of Topic 4 that you are testifying on behalf of 16 Mallinckrodt today is, quote, your interactions with 17 the DEA regarding the scheduling of controlled 18 substances, the setting of quotas, or the distribution 19 of controlled substances, including compliance, 20 regulatory and administrative actions, communications, 21 and penalties, end quote. 22 Is that consistent with your understanding 23 that you're testifying on behalf of Mallinckrodt on 24 that topic?</p>
<p style="text-align: right;">Page 15</p> <p>1 monitoring and potential diversion? 2 A. Yes. 3 Q. Is that correct? 4 A. Yes. 5 Q. And just so the record is clear, let me 6 read into the record the topic as I understand that you 7 are testifying on behalf of Mallinckrodt today. 8 And that would be, quote, the role of 9 wholesalers, distributors, and pharmacies, including 10 but not limited to defendants, in the supply chain for 11 your opioid products and the responsibilities of each 12 with respect to suspicious order monitoring and 13 potential diversion, end quote. 14 Do you understand to be testifying on that 15 topic today? 16 A. Yes. 17 Q. Great. Now, in addition you are also 18 testifying on behalf of Mallinckrodt for portions of 19 Topic 3; is that correct? 20 A. Yes. 21 Q. And again, just so the record is clear, 22 let me read the portion of Topic 3 that I believe that 23 you are testifying on behalf of Mallinckrodt. 24 And that would be, quote, warning letters</p>	<p style="text-align: right;">Page 17</p> <p>1 A. Yes. 2 Q. Great. I also understand that you are 3 testifying on behalf of Mallinckrodt on Topic 5. Is 4 that correct? 5 A. Yes. 6 Q. And in addition Topic 6? 7 A. Yes. 8 Q. Also Topic 7? 9 A. Yes. 10 Q. And turning to the next page, on Page 7, 11 there is also Topics 14 and 15. It's my understanding 12 that you are testifying on behalf of Mallinckrodt on 13 those topics. Is that accurate? 14 A. Yes to 14. Yes to 15. 15 Q. Great. And then finally if you move 16 forward to Page 11, I understand you are also being 17 designated to speak on behalf of Mallinckrodt on 18 portions of topic 27. Is that accurate? 19 A. Yes. 20 Q. And again, so the record is clear, the 21 portion of 27 that you will be testifying on 22 Mallinckrodt today is, quote, to the extent not 23 encompassed within other topics, your suspicious order 24 monitoring and compliance concerning your generic</p>

<p style="text-align: right;">Page 18</p> <p>1 opioid products. Is that accurate?</p> <p>2 A. Yes.</p> <p>3 Q. Great. Thank you for that.</p> <p>4 MR. O'CONNOR: Counsel, just for clarity.</p> <p>5 MR. KO: Sure.</p> <p>6 MR. O'CONNOR: I think on Number 4, per</p> <p>7 our letter of October 15th, Mr. Webb was testified --</p> <p>8 or was designated to testify regarding all of 4 except</p> <p>9 for the setting of quotas, and it's only the setting of</p> <p>10 quotas that's within Mr. Gillies's topics.</p> <p>11 MR. KO: And Andrew, I believe that you</p> <p>12 had sent an e-mail in early January before Mr. Webb's</p> <p>13 deposition clarifying that actually Mr. Webb was only</p> <p>14 testifying on behalf of communications, interactions</p> <p>15 with the FDA.</p> <p>16 MR. O'CONNOR: Okay.</p> <p>17 MR. KO: And I had sent a follow-up e-mail</p> <p>18 confirming.</p> <p>19 MR. O'CONNOR: Happy to confirm that at</p> <p>20 the next break, and we can handle it --</p> <p>21 MR. KO: I think regardless, some of the</p> <p>22 questions that I'll be asking today, just for your</p> <p>23 edification, that relate to the DEA could fall under</p> <p>24 other categories.</p>	<p style="text-align: right;">Page 20</p> <p>1 Q. Any other additional counsel?</p> <p>2 A. Mr. Davison.</p> <p>3 Q. And approximately how many times did you</p> <p>4 meet with them?</p> <p>5 A. Four or five. Four in person, one</p> <p>6 videoconference.</p> <p>7 Q. And when was the date of the first</p> <p>8 preparation session?</p> <p>9 A. I believe it was in September of 2018.</p> <p>10 Q. And approximately how many hours would you</p> <p>11 say you have spent preparing for this deposition?</p> <p>12 A. Approximately 80 hours total.</p> <p>13 Q. And when you said a moment ago that you're</p> <p>14 reviewing documents -- well, strike that.</p> <p>15 The 80 hours in preparation -- are those</p> <p>16 all hours you spent with counsel, or are you talking</p> <p>17 about additional hours that you spent on your own</p> <p>18 preparing?</p> <p>19 A. No, that would be a combination of counsel</p> <p>20 and individual.</p> <p>21 Q. Understood. Approximately how many hours</p> <p>22 did you meet with counsel?</p> <p>23 A. Approximately 40.</p> <p>24 Q. Okay, great. And when you said a moment</p>
<p style="text-align: right;">Page 19</p> <p>1 MR. O'CONNOR: Fair enough. Thank you.</p> <p>2 MR. KO: So if it becomes an issue, we can</p> <p>3 discuss and put it on the record.</p> <p>4 MR. O'CONNOR: Okay.</p> <p>5 BY MR. KO:</p> <p>6 Q. Now, for the topics that we went over</p> <p>7 today just a moment ago, again, just so the record is</p> <p>8 clear, you understand that you are speaking on behalf</p> <p>9 of Mallinckrodt; correct?</p> <p>10 A. Yes.</p> <p>11 Q. And you are not testifying in your</p> <p>12 individual capacity?</p> <p>13 A. Correct.</p> <p>14 Q. And you understand that your testimony</p> <p>15 will bind Mallinckrodt; is that correct?</p> <p>16 A. Yes.</p> <p>17 Q. Great. Mr. Gillies, what did you do to</p> <p>18 prepare for this deposition?</p> <p>19 A. I met with counsel a number of times,</p> <p>20 reviewed policies, procedures, e-mails, other</p> <p>21 documents.</p> <p>22 Q. And when you said counsel, is that Mr.</p> <p>23 O'Connor and Mr. Goldstein here?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 21</p> <p>1 ago you were -- that you reviewed some documents, were</p> <p>2 these all documents that were selected by your counsel?</p> <p>3 MR. O'CONNOR: You can answer that.</p> <p>4 A. Yes.</p> <p>5 BY MR. KO:</p> <p>6 Q. In other words, did you provide any</p> <p>7 documents to your counsel or did you independently</p> <p>8 review any documents on your own outside of counsel's</p> <p>9 presence?</p> <p>10 A. No.</p> <p>11 Q. Great. And have you reviewed any of the</p> <p>12 court pleadings in the national opioid litigation?</p> <p>13 A. So can you further define that for me?</p> <p>14 Q. Sure. Have you looked at the applicable</p> <p>15 complaints in this action?</p> <p>16 A. Yes.</p> <p>17 Q. Which ones?</p> <p>18 A. The original one.</p> <p>19 Q. Got it. And I'm not trying to put you</p> <p>20 through a legal test at all.</p> <p>21 A. No --</p> <p>22 Q. I'm just trying to get an understanding of</p> <p>23 what documents you may have looked at. So were these</p> <p>24 documents also selected by counsel?</p>

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1 A. Yes.

2 Q. Great. In addition to complaints, were

3 there any other pleadings or documents that looked

4 similar to, for example, the 30(b)6 notice that's in

5 front of you that you reviewed?

6 A. I would have looked at this document, but

7 I don't recall seeing anything else like this.

8 Q. Okay. Thanks. And in preparation for

9 this deposition, did you speak with any current or

10 former employees at Mallinckrodt?

11 A. Yes.

12 Q. Which ones?

13 A. Karen Harper.

14 Q. And when did you speak with her?

15 A. It would have been in January.

16 Q. January of this year?

17 A. I'm sorry. January 2019.

18 Q. Great. And did you speak with her

19 specifically about your deposition, or this case, or

20 what did you guys discuss?

21 A. Would have discussed a question I had on

22 one of these topics.

23 Q. I see. And which topic was that?

24 MR. O'CONNOR: And counsel, I'm going to

Page 23

1 object to the extent some of that discussion took place

2 in the presence of counsel and instruct the witness not

3 to answer under attorney-client privilege.

4 MR. KO: Okay.

5 BY MR. KO:

6 Q. Do you recall -- are you going to follow

7 that instruction?

8 A. Yes.

9 Q. Okay. Do you recall which topic you

10 discussed with Ms. Harper?

11 MR. O'CONNOR: Same objection, same

12 instruction.

13 BY MR. KO:

14 Q. Other than Ms. Harper, did you speak with

15 any other current or former Mallinckrodt employee

16 outside the presence of counsel?

17 A. No.

18 Q. And I'm sure you're aware that there are

19 other depositions taking place in this case of

20 Mallinckrodt current and former employees; correct?

21 A. Yes.

22 Q. And did you review any transcripts of

23 these depositions?

24 A. No.

Page 24

1 Q. And Mr. Gillies, I assume that

2 Mallinckrodt is paying for your representation by

3 Andrew and Joshua today. Is that correct?

4 A. Are they paying me or paying them? I'm

5 sorry. I don't understand the question.

6 Q. Are you being compensated in any way for

7 your testimony today individually?

8 A. I mean, I'm employed by Mallinckrodt, so

9 my compensation comes from my employer.

10 Q. Outside of your regular compensation, are

11 you getting any additional compensation?

12 A. No.

13 Q. And are you paying for your counsel both

14 in terms of preparation for this deposition and/or

15 conducting this deposition?

16 A. Me personally?

17 Q. Yes.

18 A. No.

19 Q. Great. You can set that aside. You may

20 want to refer to it from time to time, but I'll just --

21 we can move that aside for the moment.

22 A. Okay.

23 Q. Mr. Gillies, you are currently director of

24 global security at Mallinckrodt; is that correct?

Page 25

1 A. I'm currently the vice-president of global

2 security.

3 Q. Vice-president. Thanks for the

4 clarification. Have you ever been a director of global

5 security or a director at Mallinckrodt?

6 A. Yes.

7 Q. And how long -- or how long ago was that

8 when you first became director?

9 A. Yes. I was director when I joined

10 Mallinckrodt in June of 2012.

11 Q. And are you still currently a director or

12 are you no longer a director?

13 A. So I'm no longer a director.

14 Q. And when did that occur that you no longer

15 became a director?

16 A. I can't recall the exact date, but I

17 believe it was 2015.

18 Q. And so you have been vice-president of

19 global security since 2015?

20 A. Correct.

21 Q. And you said a moment ago that you became

22 director in 2012. Is that also when you joined

23 Mallinckrodt?

24 A. Yes.

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1 Q. And approximately when in 2012?
 2 A. June of 2012.
 3 Q. Is it accurate to say that currently one
 4 of your primary responsibilities is to oversee
 5 Mallinckrodt's compliance with the Controlled
 6 Substances Act?
 7 A. I'm one of the members of the suspicious
 8 order monitoring team.
 9 Q. And in addition to being one of the
 10 members of the suspicious order monitoring team, do you
 11 have additional duties to ensure that Mallinckrodt
 12 complies with its duties under the Controlled
 13 Substances Act?
 14 MR. O'CONNOR: Objection to form.
 15 A. Yes.
 16 BY MR. KO:
 17 Q. And for purposes of the deposition today,
 18 is it okay if I refer to the Controlled Substances Act
 19 as the CSA?
 20 A. Yes.
 21 Q. And okay to refer to suspicious order
 22 monitoring as SOM?
 23 A. Yes.
 24 Q. Okay, great. And I assume that you're

Page 27

1 familiar with the CSA; correct?
 2 A. Yes.
 3 Q. And you're familiar that a fundamental
 4 duty of any registrant of the CSA is to maintain
 5 effective controls against diversion?
 6 MR. O'CONNOR: Objection to form.
 7 A. Yes.
 8 BY MR. KO:
 9 Q. And is it also fair to say that one of the
 10 fundamental duties of the CSA is for a registrant to
 11 design and implement a system to identify and detect
 12 suspicious orders?
 13 MR. O'CONNOR: Objection to form.
 14 A. Yes.
 15 BY MR. KO:
 16 Q. And you would certainly agree that
 17 Mallinckrodt as a registrant of the CSA has these
 18 duties; correct?
 19 MR. O'CONNOR: Objection to form.
 20 A. Yes.
 21 BY MR. KO:
 22 Q. Now, is it accurate to state that
 23 Mallinckrodt did not always comply with these duties?
 24 MR. O'CONNOR: Objection to form.

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1 A. No.
 2 BY MR. KO:
 3 Q. Well, you're familiar with the memorandum
 4 of understanding between the DEA and Mallinckrodt;
 5 correct?
 6 A. Yes.
 7 Q. And we'll get into more of the details
 8 later, but you're familiar with all the provisions of
 9 the memorandum of understanding; is that fair?
 10 A. Yes.
 11 Q. And in the memorandum of understanding
 12 there is a provision referenced in that agreement
 13 titled admission of responsibility.
 14 Are you familiar with that provision?
 15 MR. O'CONNOR: Objection to form.
 16 A. Yes.
 17 BY MR. KO:
 18 Q. And we can refer to the document later if
 19 we need to, but in that provision there's a statement
 20 that indicates that Mallinckrodt from certain times
 21 through -- from 2008 to 2012 did not always comply with
 22 the standard set forth in DEA letters in 2006 and 2007
 23 regarding its suspicious order monitoring program.
 24 Isn't that accurate?

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1 MR. O'CONNOR: Objection to form.
 2 A. That's my understanding without reading
 3 that document.
 4 BY MR. KO:
 5 Q. So we had just talked about one of the
 6 duties under the CSA being a registrant's obligation to
 7 design and implement a system to identify suspicious
 8 orders.
 9 Do you recall that?
 10 A. I'm sorry. Could you say that again?
 11 Q. Sure. We had just talked about one of the
 12 duties under the CSA being a registrant's obligation to
 13 design and implement a system to identify suspicious
 14 orders.
 15 A. Yes.
 16 Q. And in the admission of responsibility in
 17 the MOU, memorandum of understanding, between
 18 Mallinckrodt and DEA, Mallinckrodt acknowledged that
 19 from certain times from 2008 through 2012 it did not
 20 always follow the recommendations set forth in DEA
 21 letters in 2006 and 2007 regarding SOM programs.
 22 Isn't that accurate?
 23 MR. O'CONNOR: Objection to form.
 24 A. No. No.

<p style="text-align: right;">Page 30</p> <p>1 BY MR. KO:</p> <p>2 Q. Well, we'll get to the MOU later, then.</p> <p>3 A. Okay.</p> <p>4 Q. Again, I don't want this to be a memory</p> <p>5 test or anything.</p> <p>6 A. Yeah.</p> <p>7 Q. So we'll talk about those provisions</p> <p>8 later.</p> <p>9 Going back to your background, I've seen</p> <p>10 in certain documents that you have a BA in accounting</p> <p>11 in business from Illinois State. Is that correct?</p> <p>12 A. A bachelor's of science.</p> <p>13 Q. Sorry. I apologize for that. A</p> <p>14 bachelor's of -- so you have a bachelor's of science in</p> <p>15 accounting and business administration from Illinois</p> <p>16 State. Is that correct?</p> <p>17 A. That's correct. Uh-huh.</p> <p>18 Q. And you graduated in 1982?</p> <p>19 A. Yes.</p> <p>20 Q. And after graduation you went to work for</p> <p>21 the FBI, is my understanding. Is that correct?</p> <p>22 A. Yes.</p> <p>23 Q. And was that immediately after graduation?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 32</p> <p>1 A. Until June 2012.</p> <p>2 Q. When you went to go work for Mallinckrodt?</p> <p>3 A. That's correct.</p> <p>4 Q. And both as a special agent in charge of</p> <p>5 the Miami division of the FBI and even prior to that, I</p> <p>6 want to get an understanding of when you first became</p> <p>7 aware of the opioid crisis.</p> <p>8 MR. O'CONNOR: Again, you can answer at a</p> <p>9 general level. As we discussed, there's Touhy</p> <p>10 regulations that govern his ability to speak to</p> <p>11 confidential information, so at a very high level you</p> <p>12 can answer whether you were aware.</p> <p>13 A. It would have been during that time</p> <p>14 between 2009 and 2012.</p> <p>15 BY MR. KO:</p> <p>16 Q. So you -- and during that time, given that</p> <p>17 you were in Florida, I presume that you became aware of</p> <p>18 certain issues with respect to the opioid crisis in</p> <p>19 Florida in particular as well; correct?</p> <p>20 MR. O'CONNOR: Again, you can speak to</p> <p>21 your general awareness to the extent you don't reveal</p> <p>22 any confidential government information subject to the</p> <p>23 Touhy regulations. And if you can't answer, then I</p> <p>24 would object and instruct you not to.</p>
<p style="text-align: right;">Page 31</p> <p>1 Q. What did you do between graduation and</p> <p>2 working for the FBI?</p> <p>3 A. I was doing accounting work, and I joined</p> <p>4 the FBI in October of 1983.</p> <p>5 Q. And where did you do your accounting work?</p> <p>6 A. It was in Chicago.</p> <p>7 Q. Who was your employer?</p> <p>8 A. It was Curtis Kruber (ph) -- Kruber, CPA.</p> <p>9 Excuse me.</p> <p>10 Q. And when you went to work for the FBI,</p> <p>11 what was your first job at the FBI?</p> <p>12 A. It was a general support position.</p> <p>13 Q. General support in what division?</p> <p>14 A. Chicago division.</p> <p>15 Q. In what department?</p> <p>16 A. It was for the entire office.</p> <p>17 Q. I see. And I don't want to go over too</p> <p>18 much of your background. There's -- as you understand,</p> <p>19 you have a deposition under your personal capacity</p> <p>20 tomorrow. But I just -- I do want to understand when</p> <p>21 you became a special agent in charge of the Miami</p> <p>22 division.</p> <p>23 A. October of 2009.</p> <p>24 Q. And how long were you in that role?</p>	<p style="text-align: right;">Page 33</p> <p>1 A. Could you restate that question? I'm</p> <p>2 sorry about that.</p> <p>3 BY MR. KO:</p> <p>4 Q. Sure, I can repeat it.</p> <p>5 A. Yeah, could you repeat it? That's fine.</p> <p>6 Q. Given that you were in Florida, I presume</p> <p>7 that you became aware of certain issues with respect to</p> <p>8 the opioid crisis in Florida in particular; correct?</p> <p>9 MR. O'CONNOR: Object to the form, and</p> <p>10 give the same instruction with respect to the Touhy</p> <p>11 issue.</p> <p>12 A. I'm going to take my counsel's advice on</p> <p>13 that.</p> <p>14 BY MR. KO:</p> <p>15 Q. Sure. And Mr. Gillies, I'm certainly not</p> <p>16 trying to pry into anything that might be confidential</p> <p>17 or violate any of your obligations under the law. I'm</p> <p>18 just trying to get a general understanding of whether</p> <p>19 or not you became aware of certain issues in Florida</p> <p>20 related to the opioid crisis in the 2009 through 2012</p> <p>21 time period.</p> <p>22 MR. O'CONNOR: Going to make the same</p> <p>23 objections.</p> <p>24 A. I'm going to have to take my counsel's</p>

<p style="text-align: right;">Page 34</p> <p>1 advice on that.</p> <p>2 BY MR. KO:</p> <p>3 Q. Okay. Let me try this way. Mr. Gillies,</p> <p>4 there's certainly publicly available information about</p> <p>5 the role you played with respect to certain</p> <p>6 investigations that occurred in Florida.</p> <p>7 Are you aware of those?</p> <p>8 A. Yes.</p> <p>9 Q. So I'm just asking with respect to the</p> <p>10 publicly available information out there that suggests</p> <p>11 that you played a role in, for example, prosecution of</p> <p>12 certain pill mills in Florida, I just want to make sure</p> <p>13 that the record is clear today.</p> <p>14 At some point in time during the 2009 and</p> <p>15 2012 time period, or perhaps before, you became aware</p> <p>16 that there were certain issues with respect to the</p> <p>17 opioid crisis in Florida; is that fair?</p> <p>18 MR. O'CONNOR: Object to form. You can</p> <p>19 answer with respect to publicly available information.</p> <p>20 A. Yes.</p> <p>21 BY MR. KO:</p> <p>22 Q. Now, is it also accurate to say -- putting</p> <p>23 aside your role in the FBI, is it also accurate to say</p> <p>24 that Mallinckrodt became aware of certain issues in</p>	<p style="text-align: right;">Page 36</p> <p>1 unscrupulous doctors writing scripts for opioids as</p> <p>2 early as 2008?</p> <p>3 MR. O'CONNOR: Objection to form.</p> <p>4 A. I don't have any recollection of it being</p> <p>5 2008.</p> <p>6 BY MR. KO:</p> <p>7 Q. I've probably seen a lot more documents</p> <p>8 than you have.</p> <p>9 A. I'm sure you have.</p> <p>10 Q. But have you in any of your review of</p> <p>11 documents as selected by counsel today, did you see any</p> <p>12 reference to a growing opioid crisis and problems in</p> <p>13 Florida in particular earlier than 2008?</p> <p>14 A. No.</p> <p>15 Q. And again, all these documents were</p> <p>16 selected by your counsel, is that correct, that you</p> <p>17 reviewed in preparation for this deposition?</p> <p>18 A. Yes.</p> <p>19 Q. Mr. Gillies, you are aware of the</p> <p>20 controlled substance compliance group at Mallinckrodt;</p> <p>21 is that correct?</p> <p>22 A. Yes.</p> <p>23 Q. And were you ever a member or are</p> <p>24 currently a member of the controlled substance</p>
<p style="text-align: right;">Page 35</p> <p>1 Florida as alerted by the DEA?</p> <p>2 MR. O'CONNOR: Object to form.</p> <p>3 A. Mallinckrodt became aware of the full</p> <p>4 scope of the problem after a DEA meeting in August of</p> <p>5 2011.</p> <p>6 BY MR. KO:</p> <p>7 Q. And setting aside your answer with respect</p> <p>8 to the full scope of the problem, Mallinckrodt</p> <p>9 understood that there were certain issues with respect</p> <p>10 to the Mallinckrodt pills being diverted in Florida</p> <p>11 prior to that meeting as well; correct?</p> <p>12 MR. O'CONNOR: Objection to form.</p> <p>13 A. Mallinckrodt was aware of an opioid</p> <p>14 problem, and they were aware of unscrupulous doctors</p> <p>15 writing scripts for opioids.</p> <p>16 BY MR. KO:</p> <p>17 Q. And what time period were they aware of</p> <p>18 this?</p> <p>19 A. Again, they became aware of the full scope</p> <p>20 after the August 2011 DEA meeting, so they were aware</p> <p>21 of unscrupulous doctors and some opioid issues prior to</p> <p>22 that.</p> <p>23 Q. And would it be accurate to say that they</p> <p>24 became aware of an opioid problem and aware of</p>	<p style="text-align: right;">Page 37</p> <p>1 compliance group?</p> <p>2 A. I am a member of the SOM team, and we have</p> <p>3 a DEA compliance group. Is that what you're referring</p> <p>4 to?</p> <p>5 Q. Well, that's actually helpful to clarify,</p> <p>6 because I've seen plenty of references in the documents</p> <p>7 to both a DEA compliance team and a controlled</p> <p>8 substance compliance team.</p> <p>9 Is it your testimony that there are two</p> <p>10 distinct teams, or are they the same but just used</p> <p>11 interchangeably?</p> <p>12 MR. O'CONNOR: Objection to form.</p> <p>13 A. So I'm sorry. I'm not familiar with that</p> <p>14 second term, the controlled substance compliance team.</p> <p>15 I am familiar with the DEA compliance team.</p> <p>16 BY MR. KO:</p> <p>17 Q. Got it. And what are the general roles</p> <p>18 and responsibilities of the DEA compliance team?</p> <p>19 A. I'm not part of that team, so my general</p> <p>20 understanding is that that team works closing with DEA</p> <p>21 on any issues -- that's where the quota numbers are</p> <p>22 prepared from.</p> <p>23 Q. In addition to quota, anything else?</p> <p>24 A. I'm sure there are. I'm just not part of</p>

<p style="text-align: right;">Page 38</p> <p>1 that team, so I can't give you a list.</p> <p>2 Q. And a moment ago you said you were part of</p> <p>3 the SOM team. Is the SOM team under the umbrella of</p> <p>4 the DEA compliance team, or is it a separate group?</p> <p>5 A. Separate.</p> <p>6 Q. And currently who are the members of the</p> <p>7 SOM team?</p> <p>8 A. So we have a representative from DEA</p> <p>9 compliance, from security, from legal, and government</p> <p>10 compliance.</p> <p>11 Q. And --</p> <p>12 A. There may be others.</p> <p>13 Q. And is the representative from security --</p> <p>14 is that you?</p> <p>15 A. Yes.</p> <p>16 Q. And the representatives from legal -- who</p> <p>17 are they?</p> <p>18 MR. O'CONNOR: You can answer that.</p> <p>19 A. Don Lohman, general counsel.</p> <p>20 BY MR. KO:</p> <p>21 Q. Is he the only representative of legal on</p> <p>22 the SOM team?</p> <p>23 A. Jason Tilly.</p> <p>24 Q. Is he also --</p>	<p style="text-align: right;">Page 40</p> <p>1 compliance team?</p> <p>2 MR. O'CONNOR: Objection to form.</p> <p>3 A. I'm unaware of the SOM team being under</p> <p>4 the umbrella of DEA compliance.</p> <p>5 BY MR. KO:</p> <p>6 Q. And is it -- so is it your test -- well,</p> <p>7 strike that.</p> <p>8 Did Mallinckrodt always have an</p> <p>9 independent and separate SOM team?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. So can you define always?</p> <p>12 BY MR. KO:</p> <p>13 Q. How about from the period of 2008 to the</p> <p>14 period of when you joined in June of 2012, do you have</p> <p>15 an understanding of whether or not the SOM team was</p> <p>16 independent of any other group at Mallinckrodt?</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. Yes, I believe them to be independent.</p> <p>19 BY MR. KO:</p> <p>20 Q. Now, turning back to your testimony a</p> <p>21 moment ago about how Mallinckrodt became aware of the</p> <p>22 full scope of the problem in Florida after an August</p> <p>23 23rd, 2011, meeting.</p> <p>24 Is it accurate to state that Mallin -- or</p>
<p style="text-align: right;">Page 39</p> <p>1 A. Associate general counsel.</p> <p>2 Q. And then you mentioned government</p> <p>3 compliance a moment ago. Who is the individual that is</p> <p>4 the representative on the SOM team from that group?</p> <p>5 A. Gail Tetzlaff.</p> <p>6 Q. And have you been a member of the SOM team</p> <p>7 ever since you joined Mallinckrodt in June of 2012?</p> <p>8 A. Yes.</p> <p>9 Q. And was there ever a period of time in</p> <p>10 which you were not a member of the SOM compliance team</p> <p>11 during the time period between June 2012 and current?</p> <p>12 A. I've been a member of the SOM team since I</p> <p>13 joined Mallinckrodt.</p> <p>14 Q. So in your review of documents and in</p> <p>15 preparing for this deposition today, did you see any</p> <p>16 reference to a controlled substance compliance group</p> <p>17 that was ever formed?</p> <p>18 A. I have no recollection of that, but if you</p> <p>19 have a document, I'll look at it.</p> <p>20 Q. Sure. Is it your understanding that prior</p> <p>21 to your employment at Mallinckrodt that the DEA</p> <p>22 compliance team was always separate from an SOM team,</p> <p>23 or was there ever a point in Mallinckrodt's history</p> <p>24 where the SOM team was under the umbrella of the DEA</p>	<p style="text-align: right;">Page 41</p> <p>1 excuse me -- that the DEA focused particularly on</p> <p>2 Mallinckrodt opioids, oxy 15s and oxy 30s in</p> <p>3 particular?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. I don't know if I heard you misspeak, but</p> <p>6 August of 2011. Correct?</p> <p>7 BY MR. KO:</p> <p>8 Q. Okay. I may have misspoken, and let me</p> <p>9 rephrase my question in any event to make it --</p> <p>10 A. Okay.</p> <p>11 Q. -- hopefully a little more simple. The</p> <p>12 DEA met with Mallinckrodt many times during the 2009</p> <p>13 through 2012 time period; is that fair to say?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. I don't know about many times, but we met</p> <p>16 with DEA.</p> <p>17 BY MR. KO:</p> <p>18 Q. Did Mallinckrodt meet with DEA on more</p> <p>19 occasions than the August 23rd, 2011, meeting?</p> <p>20 A. I'm sorry. Could you give me that date</p> <p>21 again?</p> <p>22 Q. Sure. I believe that you said that the</p> <p>23 meeting was in August of 2011.</p> <p>24 A. That's correct.</p>

<p style="text-align: right;">Page 42</p> <p>1 Q. And I believe in particular it was August 2 23rd of 2011. 3 A. Okay. 4 Q. That's what I -- 5 A. That's what it was, you throwing the 23rd 6 at me. I'm sorry. I don't have the exact date on 7 that. That's why I was using August of 2011. That's 8 where you were throwing me off. Okay, I'm sorry. Now 9 I understand. Okay. 10 Q. So in addition to the August 2011 meeting 11 with DEA, Mallinckrodt had additional meetings with DEA 12 regarding diversion of Mallinckrodt opioids; is that 13 fair to say? 14 MR. O'CONNOR: Objection to form. 15 A. We -- Mallinckrodt had additional meetings 16 with the DEA. It wasn't necessarily for that purpose. 17 BY MR. KO: 18 Q. What other purposes were they for? 19 A. They inspect our facilities, and so some 20 of the meetings were about inspections of our 21 facilities. 22 Q. Sure. And I understand there are a 23 variety of purposes or a variety of reasons for why DEA 24 met with Mallinckrodt, but with respect to diversion of</p>	<p style="text-align: right;">Page 44</p> <p>1 Mall -- one of DEA's focuses were the diversion of 2 Mallinckrodt opioids, and in particular the diversion 3 of Mallinckrodt oxy 15s and 30s; is that accurate? 4 A. The discussion was about Mallinckrodt 5 oxycodone products going into Florida. 6 Q. And in particular oxy 15s and oxy 30s, or 7 just oxycodone products in general? 8 A. 15s and 30s. 9 Q. So is it fair to say that Mallinckrodt 10 knew that Mallinckrodt-manufactured opioids were being 11 abused and diverted in Florida? 12 MR. O'CONNOR: Objection to form. 13 A. I don't know about the abuse part, but 14 they would have become aware of some of the diversion 15 of the products. 16 BY MR. KO: 17 Q. And what's your understanding of 18 diversion, Mr. Gillies? 19 A. Outside the legal supply chain. So if you 20 write me a legitimate script and I get it filled and I 21 give to it people around this table, there's diversion 22 there. One of the other things we could also do is we 23 could have an employee that diverts product. 24 Q. And could diversion lead to abuse of a</p>
<p style="text-align: right;">Page 43</p> <p>1 Mallinckrodt opioids, is it your testimony today that 2 Mallinckrodt only met once with DEA regarding diversion 3 of Mallinckrodt opioids? 4 A. During which time frame again? I'm sorry. 5 Q. At any time. 6 A. No. 7 Q. So in addition to the August 2011 meeting 8 between Mallinckrodt and DEA, there were additional 9 meetings, were there not, where diversion of 10 Mallinckrodt opioids was discussed between Mallinckrodt 11 and DEA; is that fair to say? 12 A. Yes. 13 Q. And a moment ago I had referred to oxy 15s 14 and oxy 30s. It's your understanding that Mallinckrodt 15 manufactured generic oxycodone in the 15-milligram 16 strength; is that accurate? 17 A. Yes. 18 Q. And in addition, Mallinckrodt also 19 manufactured oxycodone 30? 20 A. Yes. 21 Q. And for purposes of the deposition today, 22 is it okay if I refer to those as oxy 15s and oxy 30s? 23 A. Yes. 24 Q. During the August 2011 meeting, one of</p>	<p style="text-align: right;">Page 45</p> <p>1 product? 2 MR. O'CONNOR: Objection to form. 3 A. It could. 4 BY MR. KO: 5 Q. And would you agree that diversion of an 6 opioid product could also lead to its misuse? 7 A. Could. 8 Q. Is it fair to say that Mallinckrodt was 9 also aware of the Oxy Express? 10 MR. O'CONNOR: Objection to form. 11 A. I'm not aware of Mallinckrodt being aware 12 of the Oxy Express. 13 BY MR. KO: 14 Q. During both the August 2011 meetings and 15 other meetings, did DEA ever inform or discuss the Oxy 16 Express with Mallinckrodt? 17 MR. O'CONNOR: Objection to form. 18 A. Not that I'm aware of. 19 BY MR. KO: 20 Q. And in your review of documents today in 21 preparation for this deposition as selected by counsel, 22 did you see any references to the Oxy Express? 23 A. I did not. 24 Q. Do you have an understanding of what the</p>

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1 Oxy Express is?

2 MR. O'CONNOR: Objection. To the -- I'm

3 assuming, counsel, you are asking him in his capacity

4 as an employee of Mallinckrodt did he learn about that

5 term. Otherwise, there's Touhy implications.

6 So you can answer to the extent that it's

7 based on Mallinckrodt knowledge.

8 A. No.

9 BY MR. KO:

10 Q. You don't have any understanding of what

11 the Oxy Express is?

12 MR. O'CONNOR: Same --

13 BY MR. KO:

14 Q. And I know that you keep looking at

15 counsel, but I'd ask that unless he actually lodges his

16 objection clearly on the record and instructs you not

17 to answer that you refrain from looking at him every

18 time that I ask you a question.

19 A. I'm not looking at him every time you ask

20 me a question, but I've got legal implications when you

21 ask me this question, so I just want to make sure that

22 I'm not overstepping my legal bounds for my

23 responsibility to my former employer.

24 So I believe I just answered your question

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1 when it came to Mallinckrodt.

2 MR. O'CONNOR: I'm going to make the same

3 objection clearly and on the record.

4 BY MR. KO:

5 Q. So you -- have you seen any documents at

6 all that -- Mallinckrodt documents that reference the

7 Oxy Express?

8 A. I have not.

9 Q. And have you had any discussions with

10 anyone regarding -- outside the presence of your

11 counsel regarding the Oxy Express?

12 A. No.

13 Q. So turning back to the DEA compliance

14 group, as it stands today, approximately how many

15 full-time employees are part of the DEA compliance

16 group?

17 A. Six or seven is my estimate.

18 Q. And do you have an understanding of how

19 that has changed over time, if at all?

20 A. I don't think it's changed much over time.

21 Q. So as far as you know, as far as the DEA

22 compliance group has been in existence, approximately

23 six to seven full-time employees have been part of that

24 group? Is that accurate?

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1 A. That's my understanding.

2 Q. And with respect to -- I know we had just

3 discussed the individuals that were part of the SOM

4 team. How many full-time employees are part of the SOM

5 team right now?

6 A. Approximately nine.

7 Q. And has that changed over time?

8 A. It's grown.

9 Q. And when -- when was the SOM team first

10 created?

11 A. I don't know the answer to that.

12 Q. We can take a look at some documents

13 later, but does it refresh your recollection at all if

14 I say that the SOM -- it's my understanding the SOM

15 team was created in 2008.

16 Is that consistent with your

17 understanding, or are we going to need to look at some

18 more documents to establish that?

19 MR. O'CONNOR: Objection to form.

20 A. I don't have an understanding of exactly

21 when it started.

22 BY MR. KO:

23 Q. Do you have a general understanding of

24 whether or not it started before 2008 or after 2008?

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1 A. I do not.

2 Q. And as we discussed before with respect to

3 the topics that are outlined in that notice, one of the

4 topics includes Mallinckrodt's suspicious order

5 monitoring system; is that accurate?

6 A. Yes.

7 Q. And you were -- you're prepared to testify

8 on behalf of the company on all things related to

9 suspicious order monitoring; is that fair?

10 A. Yes.

11 Q. And your testimony is that you don't

12 know -- today you don't -- sitting here, you don't know

13 when the SOM team began?

14 A. That's correct. I cannot recall.

15 Q. Is it -- going back to the DEA compliance

16 group, I know you had talked about certain things that

17 they were responsible for, but you couldn't recall

18 everything.

19 Is it fair to say that the DEA compliance

20 group is responsible for any DEA reporting requirement?

21 MR. O'CONNOR: Objection to form.

22 A. Yes.

23 BY MR. KO:

24 Q. And those would include any year-end ARCOS

<p style="text-align: right;">Page 50</p> <p>1 reports that Mallinckrodt has to submit to DEA; is that</p> <p>2 accurate?</p> <p>3 MR. O'CONNOR: Objection to form.</p> <p>4 A. Yes.</p> <p>5 BY MR. KO:</p> <p>6 Q. And it would also be accurate to say that</p> <p>7 the -- well, strike that.</p> <p>8 The SOM team, you have testified, is</p> <p>9 independent from the DEA compliance group. So I want</p> <p>10 to get an understanding of whether or not the DEA</p> <p>11 compliance group has any involvement in SOM whatsoever</p> <p>12 or if the SOM team runs completely independent of DEA</p> <p>13 compliance.</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 BY MR. KO:</p> <p>16 Q. So there wasn't a question there, so I'll</p> <p>17 just ask the question.</p> <p>18 Does the DEA compliance group have any</p> <p>19 responsibility over the SOM team?</p> <p>20 A. There are DEA compliance members on the</p> <p>21 SOM team.</p> <p>22 Q. And which individuals are those?</p> <p>23 A. Karen Harper, Eileen Spaulding, and</p> <p>24 Michelle -- and I can't recall her last name.</p>	<p style="text-align: right;">Page 52</p> <p>1 Act. Do you recall that?</p> <p>2 A. Yes.</p> <p>3 Q. Now, in addition to the statute --</p> <p>4 obviously it's complex and has many layers to it.</p> <p>5 With respect to suspicious order</p> <p>6 monitoring in particular, is it accurate to say that</p> <p>7 Mallinckrodt received certain letters in the 2006 and</p> <p>8 2007 time period regarding its obligations under the</p> <p>9 CSA and in particular its obligations to design and</p> <p>10 implement the suspicious order monitoring system?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. We received a DEA letter 2007 -- 2007.</p> <p>13 The 2006 letter -- I don't believe we received a copy</p> <p>14 of that until later, in 2007 or 2008.</p> <p>15 BY MR. KO:</p> <p>16 Q. Okay. I'm going to go ahead and hand you</p> <p>17 a copy of what's been marked as Gillies Exhibit 2.</p> <p>18 [Exhibit Mallinckrodt-Gillies-002</p> <p>19 marked for identification.]</p> <p>20 Q. And for the record, Gillies Exhibit 2 is</p> <p>21 MNK-T1_000273575. And then I'm also going to hand you</p> <p>22 a copy of what's going to be marked as Gillies Exhibit</p> <p>23 3.</p> <p>24 [Exhibit Mallinckrodt-Gillies-003</p>
<p style="text-align: right;">Page 51</p> <p>1 Q. Are those the only three individuals that</p> <p>2 are both part of DEA compliance and the SOM team?</p> <p>3 A. That's my understanding.</p> <p>4 Q. And going back to the DEA compliance</p> <p>5 group, in addition to quota requests and communications</p> <p>6 with DEA regarding Mallinckrodt's quota, is it also</p> <p>7 accurate to say the DEA compliance group has</p> <p>8 responsibility coordinating any audits done by DEA of</p> <p>9 Mallinckrodt facilities?</p> <p>10 A. Yes.</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 BY MR. KO:</p> <p>13 Q. Is it also accurate to say that the DEA</p> <p>14 compliance group is responsible for tracking</p> <p>15 Mallinckrodt's internal consumption of their quota</p> <p>16 request?</p> <p>17 MR. O'CONNOR: Objection --</p> <p>18 BY MR. KO:</p> <p>19 Q. Or of the annual quota allocation?</p> <p>20 MR. O'CONNOR: Objection.</p> <p>21 A. Yes.</p> <p>22 BY MR. KO:</p> <p>23 Q. Earlier we were talking about</p> <p>24 Mallinckrodt's duties under the Controlled Substances</p>	<p style="text-align: right;">Page 53</p> <p>1 marked for identification.]</p> <p>2 Q. And for the record, that ends in Bates</p> <p>3 270069.</p> <p>4 And let's start with the second exhibit --</p> <p>5 or excuse me -- Gillies Exhibit 2.</p> <p>6 A. Okay.</p> <p>7 Q. And I see that there's a cover letter, and</p> <p>8 we can talk about that in a moment, but this is -- the</p> <p>9 letter that you see attached to this e-mail is a</p> <p>10 September 27th, 2006, letter from the DEA; is that</p> <p>11 accurate?</p> <p>12 A. Yes.</p> <p>13 Q. And this -- it's signed by Joe Rannazzisi?</p> <p>14 A. Yes.</p> <p>15 Q. By the way, did you know Joe Rannazzisi</p> <p>16 prior to the time that you joined Mallinckrodt?</p> <p>17 A. No.</p> <p>18 Q. Do you know him now?</p> <p>19 A. I know who he is.</p> <p>20 Q. But you don't have a personal relationship</p> <p>21 with him?</p> <p>22 A. I do not.</p> <p>23 Q. And in addition to the letter that you see</p> <p>24 in -- that's reflected in Exhibit 2, there's another</p>

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1 letter that's in front of you that's marked as Gillies
2 Exhibit 3 that's dated December 27th, 2007; is that
3 correct?
4 A. Yes.
5 Q. And are these the two letters that we just
6 discussed a moment ago that Mallinckrodt received
7 regarding its duties under the CSA?
8 MR. O'CONNOR: Objection to form.
9 A. Yes.
10 BY MR. KO:
11 Q. And throughout today we might be referring
12 to these letters. Is it okay if we refer to these as
13 the Rannazzisi letters?
14 A. Yes.
15 Q. Okay, great. So turning back to -- I'm
16 sorry to jump around, but turning back to Gillies
17 Exhibit 2, I just want to make sure I understand your
18 testimony a moment ago.
19 You said that you don't believe that
20 Mallinckrodt received this letter immediately after it
21 was dated September 27th, 2006. Is that correct?
22 A. That's correct.
23 Q. And your testimony is that Mallinckrodt
24 received it at some point in time in 2007 or 2008?

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1 A. Correct.
2 Q. And I just want to clarify for the record.
3 If you look at the cover e-mail, you see Ms. Harper
4 sending this letter around. Is that accurate?
5 MR. O'CONNOR: Objection to form.
6 A. So this is from Karen, and the attachment
7 says DEA letter September 27th, 2006.
8 BY MR. KO:
9 Q. So I just want to clarify for the record.
10 I want to make sure that it's clear.
11 Is it accurate to say that Mallinckrodt
12 received or individuals at Mallinckrodt received this
13 letter in 2007?
14 A. The date of this is December 13th, 2007.
15 Q. So yes or no? Is it accurate to say that
16 Mallinckrodt received the September 27th, 2006,
17 Rannazzisi letter at some point in 2007?
18 A. Yes.
19 Q. And by the way, there are some individuals
20 that are referenced in this letter at Mallinckrodt,
21 including individuals by the name of Eldon Hanson and
22 Todd Forthaus. Do you see that?
23 A. Yes.
24 Q. Do you know who they are?

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1 A. I'm familiar with Eldon's name, but not
2 Todd.
3 Q. And who is Eldon Henson, and what was his
4 role at Mallinckrodt?
5 A. I'm sorry. I don't know what his role
6 was.
7 Q. Okay. Fair enough. And there are also
8 references, if you look on Pages 2 and 3 of this
9 e-mail, to Vince Kaiman and Tim Wright.
10 Do you know who those individuals are?
11 A. I do not.
12 Q. Now, if you look at the second page of
13 this e-mail. Sorry, just stick on that exhibit.
14 A. This one? Okay.
15 Q. Yeah. Thank you. So the second page of
16 that e-mail -- I'm about two-thirds of the way down --
17 there is an e-mail from Dirk Stevens to Eldon Hanson.
18 Do you see that?
19 A. Yes.
20 Q. From December 13th?
21 A. Yes.
22 Q. 10:45? And again, Eldon Hanson was a
23 Mallinckrodt employee; is that correct?
24 A. Yes.

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1 Q. And in that e-mail, he is being asked by
2 Dirk Stevens, quote, do you have a diversion policy.
3 Do you see that?
4 A. Yes.
5 Q. What is your understanding -- well, strike
6 that.
7 With respect to Mallinckrodt's obligations
8 under the CSA, and in particular its obligations to
9 design and implement an SOM program, when did
10 Mallinckrodt first memorialize in writing a policy with
11 respect to these obligations?
12 MR. O'CONNOR: Object to form.
13 A. So Mallinckrodt always had an SOM program,
14 but I do not know the date of any formal document.
15 BY MR. KO:
16 Q. When you say that Mallinckrodt always had
17 an SOM program, can you -- do you have an understanding
18 of when it first began?
19 A. I do not.
20 Q. And do you have -- I assume I know the
21 answer to this, but when Mallinckrodt first implemented
22 an SOM program, do you know if there was any policy
23 memorialized in writing regarding that program at that
24 time?

<p style="text-align: right;">Page 58</p> <p>1 A. I do not.</p> <p>2 Q. And turning to the top of the first page,</p> <p>3 the Karen Harper e-mail to Bill Ratliff. There's an</p> <p>4 occasion -- do you see -- about three lines down where</p> <p>5 she indicates that, quote, she was forwarded policy E-9</p> <p>6 for St. Louis and A-14 for WGTC regarding the same.</p> <p>7 A. Okay.</p> <p>8 Q. And for ease of reference, you can see</p> <p>9 the --</p> <p>10 A. Okay.</p> <p>11 Q. Obviously the exhibit is in front of you,</p> <p>12 but if you'd like to look at the big screen, it's there</p> <p>13 behind me as well.</p> <p>14 Do you have any understanding of what the</p> <p>15 security policy E-9 is?</p> <p>16 A. I do not.</p> <p>17 Q. Or do you have any understanding of what</p> <p>18 the A-14 for WGTC is?</p> <p>19 A. I do not.</p> <p>20 Q. Is there any indication in that e-mail</p> <p>21 that Karen Harper is actually providing anyone with the</p> <p>22 diversion policy requested in the previous e-mail we</p> <p>23 looked at?</p> <p>24 A. Could you say that again?</p>	<p style="text-align: right;">Page 60</p> <p>1 Mallinckrodt?</p> <p>2 A. No.</p> <p>3 Q. Do you know whether or not -- I -- well,</p> <p>4 strike that.</p> <p>5 Turning to this letter, there are a series</p> <p>6 of statements being made with respect to a registrant's</p> <p>7 duties around the CSA. Is that accurate?</p> <p>8 A. Yes.</p> <p>9 Q. And in the second paragraph, there is a</p> <p>10 statement made by DEA that, quote, in addition to and</p> <p>11 not in lieu of the general requirement under 21 U.S.C.</p> <p>12 823 that manufacturers and distributors maintain</p> <p>13 effective controls against diversion, DEA regulations</p> <p>14 require all manufacturers and distributors to report</p> <p>15 suspicious orders of controlled substances, Title 21</p> <p>16 CFR, 1301.74B.</p> <p>17 Did I read that portion correctly?</p> <p>18 A. That's what this letter states.</p> <p>19 Q. And so is it accurate to say that</p> <p>20 Mallinckrodt knew that the obligation to report</p> <p>21 suspicious orders of controlled substances was an</p> <p>22 additional requirement under the CSA as required by the</p> <p>23 CFRs?</p> <p>24 MR. O'CONNOR: Objection to form.</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. Let me ask it a different way. Do you</p> <p>2 have any understanding whether Mallinckrodt as of</p> <p>3 December 2007 had a written SOM policy?</p> <p>4 A. I'm unaware whether they did or did not.</p> <p>5 Q. You can set that aside and look at Gillies</p> <p>6 Exhibit 3.</p> <p>7 And so this is the second Rannazzisi</p> <p>8 letter that Mallinckrodt received from DEA; is that</p> <p>9 correct?</p> <p>10 A. Yes.</p> <p>11 Q. And there's a received stamp that</p> <p>12 indicates that Mallinckrodt in fact received this at</p> <p>13 least no later than January 4th, 2008. Is that</p> <p>14 accurate?</p> <p>15 A. Yes.</p> <p>16 Q. And this particular letter is specifically</p> <p>17 addressed to Mallinckrodt Hobart facility?</p> <p>18 A. Yes.</p> <p>19 Q. And so the record is clear, there's no</p> <p>20 dispute that Mallinckrodt received this letter;</p> <p>21 correct?</p> <p>22 A. Correct.</p> <p>23 Q. By the way, do you have an understanding</p> <p>24 of who these Rannazzisi letters were circulated to at</p>	<p style="text-align: right;">Page 61</p> <p>1 A. Yes.</p> <p>2 BY MR. KO:</p> <p>3 Q. And moving on to the second part of that</p> <p>4 sentence. The letter continues, quote -- well, strike</p> <p>5 that.</p> <p>6 The letter indicates that DEA regulations,</p> <p>7 quote, require that a registrant design and operate a</p> <p>8 system to disclose to the registrant suspicious orders</p> <p>9 of controlled substances, end quote.</p> <p>10 Did I read that correct -- portion of the</p> <p>11 paragraph correctly?</p> <p>12 A. Yes.</p> <p>13 Q. And so in addition to the duty to maintain</p> <p>14 effective controls against diversion, Mallinckrodt knew</p> <p>15 that it had to design and operate a system to disclose</p> <p>16 to the registrant suspicious orders of controlled</p> <p>17 substances; is that accurate?</p> <p>18 A. Yes.</p> <p>19 Q. And moving on to the next sentence, it</p> <p>20 indicates that the regulation -- let me be clear.</p> <p>21 The next statement states, quote, the</p> <p>22 regulation clearly indicates that it is the sole</p> <p>23 responsibility of the registrant to design and operate</p> <p>24 such a system, end quote.</p>

<p style="text-align: right;">Page 62</p> <p>1 Did I read that correctly?</p> <p>2 A. Yes.</p> <p>3 Q. And so is it fair to say that Mallinckrodt</p> <p>4 knew as of the date of receiving this letter that the</p> <p>5 DEA expected the sole responsibility to design and</p> <p>6 operate an SOM system to lie with the registrant -- in</p> <p>7 this case, Mallinckrodt?</p> <p>8 MR. O'CONNOR: Objection to form.</p> <p>9 BY MR. KO:</p> <p>10 Q. Is that correct?</p> <p>11 A. Yes.</p> <p>12 Q. Now, moving on to the third paragraph.</p> <p>13 The second sentence indicates, quote, filing a monthly</p> <p>14 report of completed transactions, for example,</p> <p>15 excessive purchase report or high unit purchases, does</p> <p>16 not meet the regulatory requirement to report</p> <p>17 suspicious orders, end quote.</p> <p>18 Did I read that correctly?</p> <p>19 A. That's what it says.</p> <p>20 Q. So is it fair to say that Mallinckrodt</p> <p>21 understood that simply filing a monthly excessive order</p> <p>22 report would not meet the regulatory requirements under</p> <p>23 the CSA?</p> <p>24 MR. O'CONNOR: Objection to form.</p>	<p style="text-align: right;">Page 64</p> <p>1 prior to completing a sale to determine whether the</p> <p>2 controlled substances are likely to be diverted from</p> <p>3 legitimate channels.</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. So again, is it fair to say that the DEA</p> <p>7 expectation as of the date of this letter was that --</p> <p>8 and Mallinckrodt in fact understood that their</p> <p>9 responsibilities do not end with merely filing a</p> <p>10 suspicious order report? Is that accurate?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. Yes.</p> <p>13 BY MR. KO:</p> <p>14 Q. In other words, Mallinckrodt must, as of</p> <p>15 the date of this letter, conduct an independent</p> <p>16 analysis of suspicious orders prior to completing a</p> <p>17 sale determine -- to determine whether the controlled</p> <p>18 substances are likely to be diverted. Is that</p> <p>19 accurate?</p> <p>20 MR. O'CONNOR: Objection.</p> <p>21 A. Yes.</p> <p>22 BY MR. KO:</p> <p>23 Q. So as of the date of this letter, it would</p> <p>24 be accurate to say that if Mallinckrodt released an</p>
<p style="text-align: right;">Page 63</p> <p>1 A. When this letter received, that was the</p> <p>2 industry standard prior.</p> <p>3 BY MR. KO:</p> <p>4 Q. And I understand, but my question was just</p> <p>5 simply a yes-or-no question.</p> <p>6 Is it fair to say that Mallinckrodt</p> <p>7 understood that simply filing a monthly excessive order</p> <p>8 report would not meet the regulatory requirements under</p> <p>9 the CSA as of the date of this letter?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. Yes.</p> <p>12 BY MR. KO:</p> <p>13 Q. So if Mallinckrodt was sending monthly</p> <p>14 reports to DEA after January 4th, 2008, that would not</p> <p>15 be consistent with the standard set forth in this</p> <p>16 letter; is that accurate?</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. Yes.</p> <p>19 BY MR. KO:</p> <p>20 Q. Going on to the next sentence, the letter</p> <p>21 indicates, that quote, registrants are reminded that</p> <p>22 their responsibility does not end merely with the</p> <p>23 filing of a suspicious order report. Registrants must</p> <p>24 conduct an independent analysis of suspicious orders</p>	<p style="text-align: right;">Page 65</p> <p>1 order prior to completing a sale and without doing any</p> <p>2 sort of independent analysis would not be consistent</p> <p>3 with the standard set forth in this letter?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. I'm sorry. Could you state that one more</p> <p>6 time?</p> <p>7 BY MR. KO:</p> <p>8 Q. Sure. Would it be accurate to say that if</p> <p>9 Mallinckrodt released an order prior to completing a</p> <p>10 sale and without doing any sort of independent</p> <p>11 analysis, that would not be consistent with the</p> <p>12 standard set forth in this letter?</p> <p>13 A. No.</p> <p>14 MR. O'CONNOR: Same objection.</p> <p>15 BY MR. KO:</p> <p>16 Q. It would not be accurate to say that?</p> <p>17 A. Correct.</p> <p>18 Q. And why is that?</p> <p>19 A. This is referring to suspicious orders.</p> <p>20 Q. I see. I see what you're saying. Let me</p> <p>21 rephrase my question.</p> <p>22 So would it be accurate to say -- well,</p> <p>23 strike that.</p> <p>24 In the third sentence that we just read,</p>

<p style="text-align: right;">Page 66</p> <p>1 the DEA provides guidance, does it not, that</p> <p>2 registrants must conduct an independent analysis of</p> <p>3 suspicious orders prior to completing a sale?</p> <p>4 A. Yes.</p> <p>5 Q. So are you suggesting that that provision</p> <p>6 only applies with respect to a suspicious order but not</p> <p>7 any other order?</p> <p>8 A. Yes, that's what the regulation says.</p> <p>9 Q. And what is your understanding of what</p> <p>10 constitutes a suspicious order?</p> <p>11 A. So DEA defines it as size, normal</p> <p>12 pattern -- and there's a third one. Yeah.</p> <p>13 Q. Well, it's actually -- it's later on in</p> <p>14 this letter, so why don't we actually turn to that</p> <p>15 portion of this letter.</p> <p>16 The fourth paragraph down at the bottom of</p> <p>17 this page states the regulation specifically states</p> <p>18 that suspicious orders include orders of an unusual</p> <p>19 size, orders deviating substantially from a normal</p> <p>20 pattern, and orders of an unusual frequency, end quote.</p> <p>21 Did I read that correctly?</p> <p>22 A. Yes.</p> <p>23 Q. So is it your understanding that a</p> <p>24 suspicious order, among other things, constitutes those</p>	<p style="text-align: right;">Page 68</p> <p>1 quantities of one particular controlled substance</p> <p>2 relative to others it orders?</p> <p>3 MR. O'CONNOR: Objection to form.</p> <p>4 A. So could you further define that?</p> <p>5 BY MR. KO:</p> <p>6 Q. Well, is one purpose -- well, would you</p> <p>7 agree with me that a pharmacy that orders 90 percent --</p> <p>8 for example, 90 percent of one particular drug relative</p> <p>9 to others would warrant further investigation?</p> <p>10 MR. O'CONNOR: Objection --</p> <p>11 A. So I'm not going to see that as the</p> <p>12 manufacturer.</p> <p>13 BY MR. KO:</p> <p>14 Q. What do you mean by that?</p> <p>15 A. I'm not selling to pharmacies. We sell to</p> <p>16 the distributors and wholesalers who sell to the</p> <p>17 pharmacies. So I'm not going to see any other product,</p> <p>18 and we're only selling the generic controlleds to the</p> <p>19 distributors and wholesalers.</p> <p>20 Q. At a certain point in time Mallinckrodt</p> <p>21 became aware and had access to information regarding</p> <p>22 downstream transactions between its wholesale</p> <p>23 distributor customers and pharmacies and clinics; is</p> <p>24 that accurate?</p>
<p style="text-align: right;">Page 67</p> <p>1 elements?</p> <p>2 A. Yes.</p> <p>3 Q. And so would it be accurate to say that</p> <p>4 one purpose of why Mallinckrodt designed and</p> <p>5 implemented a suspicious order monitoring system is to</p> <p>6 identify orders of an unusual size?</p> <p>7 A. Yes.</p> <p>8 Q. And also to identify orders that deviate</p> <p>9 substantially from a normal pattern?</p> <p>10 A. Yes.</p> <p>11 Q. And also Mallinckrodt designed and</p> <p>12 implemented an SOM program to identify orders of an</p> <p>13 unusual frequency?</p> <p>14 A. Yes.</p> <p>15 Q. Would you agree with me that one of the</p> <p>16 purposes of identifying a suspicious order is also to</p> <p>17 make sure that Mallinckrodt fills orders only for</p> <p>18 legitimate scientific and medical means?</p> <p>19 MR. O'CONNOR: Objection to form.</p> <p>20 A. Yes.</p> <p>21 BY MR. KO:</p> <p>22 Q. Now, is it also fair to say that an</p> <p>23 effective SOM program would also be able to identify</p> <p>24 whether a pharmacy or clinic is ordering excessive</p>	<p style="text-align: right;">Page 69</p> <p>1 A. With pharmacies. Not all pharmacies.</p> <p>2 Some pharmacies.</p> <p>3 Q. So yes or no? At a certain point in time,</p> <p>4 Mallinckrodt became aware and had access to information</p> <p>5 regarding downstream transactions between its wholesale</p> <p>6 distributor customers and pharmacy and clinics; is that</p> <p>7 accurate?</p> <p>8 MR. O'CONNOR: Objection to form.</p> <p>9 A. Could you restate that question or at</p> <p>10 least just repeat it one more time?</p> <p>11 BY MR. KO:</p> <p>12 Q. Sure. At a certain point in time,</p> <p>13 Mallinckrodt became aware and had access to information</p> <p>14 regarding downstream transactions between its wholesale</p> <p>15 distributor customers and pharmacies and clinics?</p> <p>16 MR. O'CONNOR: Same objection.</p> <p>17 BY MR. KO:</p> <p>18 Q. Is that accurate?</p> <p>19 A. For some of them, yes.</p> <p>20 Q. And I know that you just said a moment ago</p> <p>21 that Mallinckrodt had no visibility beyond -- or I</p> <p>22 don't -- I'm not trying to take words out of your</p> <p>23 mouth, but you seemed to imply that Mallinckrodt did</p> <p>24 not know what was going on with respect to its drugs</p>

<p style="text-align: right;">Page 70</p> <p>1 after it went to the distributor.</p> <p>2 That's not entirely accurate; is that</p> <p>3 correct?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. That wasn't your question, so that was not</p> <p>6 my response. That's a completely different thing that</p> <p>7 you're asking me now.</p> <p>8 BY MR. KO:</p> <p>9 Q. Okay. So I'll go back to my original</p> <p>10 question, then.</p> <p>11 A. Okay.</p> <p>12 Q. Wouldn't it be reflective -- well, strike</p> <p>13 that.</p> <p>14 Would you agree with me that an effective</p> <p>15 suspicious order monitoring program would be able to</p> <p>16 identify whether a pharmacy or clinic is ordering</p> <p>17 excessive quantities of a limited variety of controlled</p> <p>18 substances?</p> <p>19 MR. O'CONNOR: Objection to form.</p> <p>20 A. I'm not going to see, as the manufacturer,</p> <p>21 all the products that they are or are not ordering.</p> <p>22 BY MR. KO:</p> <p>23 Q. Yeah. Regardless of whether or not you</p> <p>24 can see, and we can talk -- discuss later about all the</p>	<p style="text-align: right;">Page 72</p> <p>1 that's going to depend on what my answer is.</p> <p>2 BY MR. KO:</p> <p>3 Q. Okay. Let's start with the manufacturers.</p> <p>4 A. No.</p> <p>5 Q. Your answer is no?</p> <p>6 A. Yes.</p> <p>7 Q. Let's turn to the top of Page 2.</p> <p>8 Actually, before we get there, I also want</p> <p>9 to ask whether or not you would agree with me that an</p> <p>10 effective SOM program would also be able to identify</p> <p>11 whether or not a pharmacy or clinic is ordering from</p> <p>12 multiple distributors with respect to the same</p> <p>13 controlled substance.</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. That would be a factor to consider.</p> <p>16 BY MR. KO:</p> <p>17 Q. And in addition to a factor to consider,</p> <p>18 would it be reflective of an effective SOM program for</p> <p>19 a registrant to determine whether or not a pharmacy or</p> <p>20 clinic is ordering the same controlled substance from</p> <p>21 multiple distributors?</p> <p>22 MR. O'CONNOR: Objection to form.</p> <p>23 A. It would be a factor to consider.</p> <p>24 BY MR. KO:</p>
<p style="text-align: right;">Page 71</p> <p>1 pieces of information that a registrant potentially</p> <p>2 could have had -- any particular manufacturing</p> <p>3 registrant.</p> <p>4 But for purposes of an SOM program -- you</p> <p>5 have responsibilities with respect to the SOM program</p> <p>6 today, do you not?</p> <p>7 A. Yes.</p> <p>8 Q. And I'm simply asking whether or not you</p> <p>9 believe -- or you would agree with me that an effective</p> <p>10 SOM program would be able to identify, regardless of</p> <p>11 whether or not you think the manufacturer can or cannot</p> <p>12 identify the details of the downstream transaction --</p> <p>13 would you agree that an effective SOM program would be</p> <p>14 able to identify whether a pharmacy or clinic is</p> <p>15 ordering excessive quantities of a limited variety of</p> <p>16 controlled substances?</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. Are you talking about my SOM program?</p> <p>19 BY MR. KO:</p> <p>20 Q. I'm talking about an effective SOM --</p> <p>21 program.</p> <p>22 A. Okay.</p> <p>23 MR. O'CONNOR: Same objection.</p> <p>24 A. Manufacturers or distributors? I mean,</p>	<p style="text-align: right;">Page 73</p> <p>1 Q. And I'm asking a yes-or-no question.</p> <p>2 A. Oh, I'm sorry.</p> <p>3 Q. Yeah. Yes or no, would it be reflective</p> <p>4 of an effective SOM program for a registrant to</p> <p>5 determine whether or not a pharmacy or clinic is</p> <p>6 ordering the same controlled substance from multiple</p> <p>7 distributors?</p> <p>8 MR. O'CONNOR: Objection to form.</p> <p>9 A. Yes.</p> <p>10 MR. O'CONNOR: Counsel, we're about an</p> <p>11 hour and 20 minutes in. Can we take a five- or</p> <p>12 10-minute break?</p> <p>13 MR. KO: Sure. Sounds good.</p> <p>14 MR. O'CONNOR: Okay.</p> <p>15 THE VIDEOGRAPHER: We are going off the</p> <p>16 record at 10:22 AM.</p> <p>17 [A brief recess was taken.]</p> <p>18 THE VIDEOGRAPHER: We are back on the</p> <p>19 record at 10:40 AM.</p> <p>20 BY MR. KO:</p> <p>21 Q. Welcome back from the break. Just a few</p> <p>22 more questions on Exhibit 3. You have it in front of</p> <p>23 you.</p> <p>24 At the top of Page 2, there's a statement</p>

<p style="text-align: right;">Page 74</p> <p>1 that says, quote, registrants that rely on rigid</p> <p>2 formulas to define whether an order is suspicious may</p> <p>3 be failing to detect suspicious orders. For example, a</p> <p>4 system that identifies orders as suspicious only if the</p> <p>5 total amount of controlled substance ordered during one</p> <p>6 month exceeds the amount ordered the previous month by</p> <p>7 a certain percentage or more is insufficient.</p> <p>8 Did I read that correctly?</p> <p>9 A. Yes.</p> <p>10 Q. So would you agree with me that</p> <p>11 Mallinckrodt knew as of the date of this letter that</p> <p>12 rigid -- adherence to a rigid formula to define whether</p> <p>13 an order is suspicious would be inadequate?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. That's what the letter says, yes.</p> <p>16 BY MR. KO:</p> <p>17 Q. So yes or no? Would you agree with me</p> <p>18 that Mallinckrodt knew as of the date of this letter</p> <p>19 that adherence to a rigid formula to identify whether</p> <p>20 an order is suspicious would be inadequate?</p> <p>21 MR. O'CONNOR: Objection to form. Asked</p> <p>22 and answered.</p> <p>23 A. Yes.</p> <p>24 BY MR. KO:</p>	<p style="text-align: right;">Page 76</p> <p>1 A. I believe we were manufacturing opioids at</p> <p>2 least from 1996.</p> <p>3 BY MR. KO:</p> <p>4 Q. And did Mallinckrodt have an SOM program</p> <p>5 since when it began manufacturing prescription opioids?</p> <p>6 A. That's my understanding.</p> <p>7 Q. But you don't have a recollection of</p> <p>8 whether or not there was a written policy at the time</p> <p>9 that first -- that Mallinckrodt first began</p> <p>10 manufacturing prescription opioids; is that accurate?</p> <p>11 A. That's correct.</p> <p>12 Q. Now, with respect to the suspicious order</p> <p>13 monitoring procedures, is it accurate to state that</p> <p>14 Mallinckrodt had at certain points a two-tiered system</p> <p>15 to identify suspicious orders?</p> <p>16 MR. O'CONNOR: Objection to form.</p> <p>17 A. Yes.</p> <p>18 BY MR. KO:</p> <p>19 Q. And I understand and I believe that there</p> <p>20 are three tiers now, but for some portion of when</p> <p>21 Mallinckrodt had an SOM program, there were two tiers</p> <p>22 with respect to identifying a suspicious order; is that</p> <p>23 correct?</p> <p>24 MR. O'CONNOR: Objection to form.</p>
<p style="text-align: right;">Page 75</p> <p>1 Q. Thank you. Now, we had discussed -- you</p> <p>2 can set this aside, actually.</p> <p>3 A. Okay.</p> <p>4 Q. Earlier we had discussed whether or not</p> <p>5 Mallinckrodt had written policies with respect to its</p> <p>6 SOM program.</p> <p>7 Do you recall that testimony?</p> <p>8 A. Yes.</p> <p>9 Q. And I know you said you don't recall when</p> <p>10 it first started, but at a certain point in time there</p> <p>11 were certain written policies that were drafted and</p> <p>12 revised and circulated within Mallinckrodt; is that</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. And when do you recall the first written</p> <p>16 policy -- or when did Mallinckrodt first begin writing</p> <p>17 or drafting these written policies?</p> <p>18 MR. O'CONNOR: Objection to form.</p> <p>19 A. I don't have any recollection of the date.</p> <p>20 BY MR. KO:</p> <p>21 Q. And you understand -- Mallinckrodt -- is</p> <p>22 it accurate to say that Mallinckrodt manufactured</p> <p>23 opioids beginning in approximately 1996?</p> <p>24 MR. O'CONNOR: Objection to form.</p>	<p style="text-align: right;">Page 77</p> <p>1 A. So I believe there's two tiers now.</p> <p>2 BY MR. KO:</p> <p>3 Q. Oh, is that -- okay. Was there ever a</p> <p>4 time that there was a three-tier system?</p> <p>5 A. Yes.</p> <p>6 Q. And with respect to the two-tiered system,</p> <p>7 the first tier -- and correct me if I'm wrong -- but</p> <p>8 the first tier attempts to identify whether an order is</p> <p>9 either peculiar or unusual; is that accurate?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. The Tier 1 of the program applies to the</p> <p>12 big three plus one regarding oxy 15s and oxy 30s.</p> <p>13 BY MR. KO:</p> <p>14 Q. And that's the two-tier structure right</p> <p>15 now that you're describing; correct?</p> <p>16 A. That's correct.</p> <p>17 Q. Let's talk about the 2008 to 2012 time</p> <p>18 period.</p> <p>19 A. Okay.</p> <p>20 Q. Did you have an understanding of whether</p> <p>21 or not there were two or three tiers during that time</p> <p>22 period?</p> <p>23 A. In --</p> <p>24 MR. O'CONNOR: Objection to form.</p>

<p style="text-align: right;">Page 78</p> <p>1 A. In early 2012, there was the three-tiered 2 system. 3 BY MR. KO: 4 Q. And so prior to -- 5 A. And then September 2012 was a two-tiered 6 system. 7 Q. Got it. Thank you. And so prior to 2012, 8 was the SOM program -- the intent of the SOM program 9 was to have a two-tiered system? 10 MR. O'CONNOR: Objection to form. 11 A. I don't know what that intent was. 12 BY MR. KO: 13 Q. Sure. Well, I was hoping not to go 14 through each -- well, we will go through some of the 15 SOM policies, but I'm just hoping to get a general 16 understanding of what your -- of the systems that 17 Mallinckrodt had in place, but we can look at the 18 policies in a moment. 19 A. Okay. 20 Q. Now, do you have an understanding of how 21 many orders Mallinckrodt has identified as being 22 suspicious? 23 A. I do not. 24 Q. You have no understanding of how many</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. And you have -- in addition to not knowing 2 exactly how many, you don't have any understanding of 3 the general amount of suspicious orders that were 4 reported to the DEA prior to 2008? 5 A. I don't. I just know that there were 6 suspicious orders reported to the DEA. 7 Q. From the period 2008 through 2011, do you 8 have any understanding of how many suspicious orders 9 were reported to the DEA? 10 A. I do not. 11 Q. I'm going to hand you a copy of what will 12 be marked as Gillies Exhibit 4 and -- 13 MS. GAFFNEY: 5. 14 BY MR. KO: 15 Q. -- 5. And for the record I'll note that 16 Gillies Exhibit 4 ends in Bates 1806623, and Exhibit 5 17 is actually the attachment which ends in 1806624. 18 [Exhibit Mallinckrodt-Gillies-004 19 marked for identification.] 20 [Exhibit Mallinckrodt-Gillies-005 21 marked for identification.] 22 Q. So Mr. Gillies, does this document look 23 familiar to you at all? 24 A. I mean, I don't recall it, but --</p>
<p style="text-align: right;">Page 79</p> <p>1 orders Mallinckrodt has notified to the DEA at any 2 point in Mallinckrodt's history as to how many orders 3 are suspicious? 4 A. I know there has been suspicious orders, 5 and I know they've been identified to the DEA. 6 Q. But you have no understanding of how many 7 orders have been identified to the DEA? 8 A. I do not. 9 Q. As you know, other depo -- other 10 individuals have been deposed in this case, and Ms. 11 Harper has testified that prior to 2008, Mallinckrodt 12 had identified approximately 10 or less suspicious 13 orders to the DEA. 14 Does that sound familiar to you at all? 15 MR. O'CONNOR: Objection to form. 16 A. It does not, but -- 17 BY MR. KO: 18 Q. Does it refresh your recollection at all 19 that Mallinckrodt had identified only a small number of 20 suspicious orders prior to 2008? 21 MR. O'CONNOR: Objection to form. 22 A. Again, I don't know how many there were 23 prior to that time. 24 BY MR. KO:</p>	<p style="text-align: right;">Page 81</p> <p>1 Q. Well, let's just take a look at the 2 first -- well, this -- for the record, this is an 3 e-mail that Karen Harper sends to you on April 25th, 4 2014. Is that accurate? 5 A. Yes. 6 Q. And at the top of the e-mail she states, 7 quote, 12-31-2003, the oldest SOM report to DEA that 8 was retrievable this evening attached. Given the 9 report number identity, we may be able to retrieve 10 older information through IS, end quote. 11 Did I read that correctly? 12 A. Yes. 13 Q. First off, IS is information systems; 14 correct? 15 A. Yes. 16 Q. And that's a group at Mallinckrodt; right? 17 A. Yes. 18 Q. And they were -- they had some 19 responsibilities with respect to the SOM program? 20 MR. O'CONNOR: Objection to form. 21 BY MR. KO: 22 Q. Is that accurate? 23 A. I don't know what their role would have 24 been. This is our IT department, and so I don't know</p>

<p style="text-align: right;">Page 82</p> <p>1 if they were just pulling records for her.</p> <p>2 Q. Sure. So that's helpful. So the IS group</p> <p>3 referenced here is essentially the IT department at</p> <p>4 Mallinckrodt; correct?</p> <p>5 A. That's correct. Yeah.</p> <p>6 Q. And does the IT department currently have</p> <p>7 a role with respect to retrieving information for</p> <p>8 purposes of Mallinckrodt's SOM program?</p> <p>9 A. Yes.</p> <p>10 Q. And they provide regular monthly reports</p> <p>11 to the SOM team; is that accurate?</p> <p>12 MR. O'CONNOR: Objection to form.</p> <p>13 A. I don't know how regularly they provide</p> <p>14 that information.</p> <p>15 BY MR. KO:</p> <p>16 Q. Now, this document indicates that the</p> <p>17 earliest SOM report, at least as of 2014, that Ms.</p> <p>18 Harper could find was from 2003. Is that accurate?</p> <p>19 A. That's what it says. And it says we may</p> <p>20 be able to retrieve older information through the IT</p> <p>21 department.</p> <p>22 Q. And have you seen any suspicious order</p> <p>23 reports prior to 2003?</p> <p>24 A. Not that I can recall.</p>	<p style="text-align: right;">Page 84</p> <p>1 peculiar?</p> <p>2 A. Yes.</p> <p>3 Q. And if that algorithm was triggered, a</p> <p>4 report was created? Is that accurate?</p> <p>5 A. Yes.</p> <p>6 Q. And the reports that are referenced here</p> <p>7 in this e-mail that were temporarily discontinued to be</p> <p>8 sent to the DEA, those are those peculiar order</p> <p>9 reports; is that accurate?</p> <p>10 A. That's my understanding.</p> <p>11 Q. And the e-mail goes on to state that the</p> <p>12 SOM team is working on a revised algorithm system, and</p> <p>13 that -- well, first of all, you see that portion of the</p> <p>14 e-mail?</p> <p>15 A. Yes.</p> <p>16 Q. And the revised algorithm system is with</p> <p>17 respect to the peculiar order algorithm; is that</p> <p>18 accurate?</p> <p>19 A. Yes.</p> <p>20 Q. And to be clear, Mallinckrodt</p> <p>21 distinguished between a peculiar order and a suspicious</p> <p>22 order; is that accurate?</p> <p>23 A. Yes.</p> <p>24 Q. And the basic structure, at least as of</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. Are you aware of any suspicious order</p> <p>2 reports prior to 2003?</p> <p>3 A. No.</p> <p>4 Q. Now, in the next sentence down, Ms. Harper</p> <p>5 indicates to you, quote, 10-2008. SOM report</p> <p>6 submission to DEA local office is temporarily</p> <p>7 discontinued per direction of DEA. SOM team begins</p> <p>8 work on revised algorithm system.</p> <p>9 Did I read that correctly?</p> <p>10 A. Yes.</p> <p>11 Q. And what is your understanding of which</p> <p>12 reports were being discontinued per the direction of</p> <p>13 the DEA?</p> <p>14 A. The peculiar order reports.</p> <p>15 Q. And is it accurate to say that those are</p> <p>16 the monthly reports that -- well, let's take a step</p> <p>17 back.</p> <p>18 What are the peculiar order reports that</p> <p>19 Mallinckrodt created prior to October of 2008?</p> <p>20 A. So they would have been the algorithm</p> <p>21 reports to show any orders regarding the unusual size,</p> <p>22 pattern, et cetera.</p> <p>23 Q. So is it fair to say that Mallinckrodt had</p> <p>24 an algorithm to determine whether or not an order was</p>	<p style="text-align: right;">Page 85</p> <p>1 the time of this e-mail and as of the time that</p> <p>2 Mallinckrodt utilized peculiar orders -- the basic</p> <p>3 structure was if an order was determined to be</p> <p>4 peculiar, it would be elevated for further review to</p> <p>5 determine whether or not it was suspicious for purposes</p> <p>6 of notifying the DEA; is that accurate?</p> <p>7 A. Correct.</p> <p>8 Q. And so when this e-mail is discussing --</p> <p>9 when Ms. Harper is discussing with you the fact that</p> <p>10 these reports are being temporarily discontinued per</p> <p>11 the direction of the DEA, what is your understanding of</p> <p>12 what Ms. Harper is referring to here?</p> <p>13 MR. O'CONNOR: Objection to form.</p> <p>14 A. She's referring to the reports that we</p> <p>15 were sending to the DEA are no longer being sent to the</p> <p>16 DEA per their direction.</p> <p>17 BY MR. KO:</p> <p>18 Q. And was -- and I guess I was unclear, and</p> <p>19 I apologize for that. The direction of the DEA -- I</p> <p>20 want to focus on that portion.</p> <p>21 Is that in reference to the Rannazzisi</p> <p>22 letters that we were just discussing a moment ago?</p> <p>23 A. Yes. The December 2007 letter.</p> <p>24 Q. Correct. And the portion of that letter</p>

<p style="text-align: right;">Page 86</p> <p>1 that discusses the concept of not sending monthly 2 excessive order reports to DEA; correct? 3 A. That's right. That was the industry 4 standard, and then in that letter they said 5 discontinue. 6 Q. And that letter, to be clear, was dated 7 December 27th and received in January of 2008; correct? 8 A. That's the date stamp on here, yes. 9 Q. And this chronology indicates that 10 Mallinckrodt stopped sending the reports in October of 11 2008; correct? 12 A. That's what this indicates, but that's not 13 what my recollection is, that we had stopped submitting 14 these reports a lot earlier than this. 15 Q. So would it be accurate to say that if 16 Mallinckrodt sent monthly reports at some point in time 17 between January of 2008 and October of 2008, that would 18 be inconsistent with the standard set forth in the 19 December 27th, 2007, Rannazzisi letter; correct? 20 MR. O'CONNOR: Objection to form. 21 A. Per the December 2007 letter, the DEA was 22 advising registrants to stop sending those reports. 23 BY MR. KO: 24 Q. So would it be accurate to say that if</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. Now, further on in this e-mail, the next 2 section down, Ms. Harper indicates 7-20-2010, DEA St. 3 Louis visits St. Louis plant for a physical security 4 inspection, and advises Mallinckrodt that DEA SOM 5 expectation is that Mallinckrodt know their customer's 6 customer. 7 Did I read that correctly? 8 A. Yes. 9 Q. So is it accurate to say that Mallinckrodt 10 knew at least as of July 20th, 2010, that the DEA 11 expected Mallinckrodt to know their customer's 12 customer? 13 MR. O'CONNOR: Objection to form. 14 A. So it's not part of the regulations, but 15 that's what DEA was advising us now, that they expected 16 us to know our customer's customer. 17 BY MR. KO: 18 Q. So is it accurate to say that as of July 19 20th, 2010, Mallinckrodt knew that the DEA expected 20 Mallinckrodt to know their customer's customer? 21 MR. O'CONNOR: Objection to form. 22 A. That's what the DEA in St. Louis advised 23 us. 24 BY MR. KO:</p>
<p style="text-align: right;">Page 87</p> <p>1 Mallinckrodt sent monthly letters to DEA between 2 January 2008 and October 2008, that practice would be 3 inconsistent with the standard set forth in the 4 December 27th, 2007, Rannazzisi letter; correct? 5 MR. O'CONNOR: Objection to form. 6 A. So to be accurate, those SOM reports. I 7 believe you used the term letter, so I just want to 8 make sure that it was -- I don't want to be confused. 9 So I think you're talking about the 10 reports; correct? 11 BY MR. KO: 12 Q. Sure. So -- 13 A. Okay. 14 Q. And you're absolutely right. Thank you 15 for the clarification. So just so the record is 16 perfectly clear, would it be fair to say that if 17 Mallinckrodt sent monthly reports to the DEA between 18 January 2008 and October 2008 regarding any kind of 19 excessive order, that practice would be inconsistent 20 with the standard set forth in the December 27th, 2007, 21 Rannazzisi letter; correct? 22 MR. O'CONNOR: Same objection. 23 A. Yes. 24 BY MR. KO:</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. And further on in that paragraph, there's 2 also an indication that Mallinckrodt begins evaluating 3 the use of chargeback data for SOM. Do you see that 4 portion of the e-mail? 5 A. Yes. 6 Q. And so at least as of July 2010, 7 Mallinckrodt -- is it fair to say that Mallinckrodt 8 began contemplating use of chargeback data in 9 connection with its suspicious order monitoring 10 program? 11 A. Yes. 12 Q. And turning to the -- actually, turning to 13 the attachment of the e-mail, which as indicated by Ms. 14 Harper's cover e-mail to you was an SOM report. Do you 15 see that? 16 A. Yes. 17 Q. And so is it fair to say that this is an 18 example of an SOM report that Mallinckrodt had created 19 and apparently sent to the DEA in 2003? 20 A. That's what it appears to be. 21 Q. And do you have any understanding of how 22 Mallinckrodt identified the suspicious orders that 23 appeared here? 24 A. Through the use of the algorithms that</p>

<p style="text-align: right;">Page 90</p> <p>1 they were utilizing.</p> <p>2 Q. So it's your testimony that Mallinckrodt</p> <p>3 utilized an algorithm as of 2003?</p> <p>4 A. Yes.</p> <p>5 Q. And separate and apart from the algorithm,</p> <p>6 do you know whether or not Mallinckrodt utilized any</p> <p>7 other elements to identify a suspicious order at that</p> <p>8 time?</p> <p>9 MR. O'CONNOR: Objection to form.</p> <p>10 Objection to form.</p> <p>11 A. The -- every order was being reviewed by a</p> <p>12 customer service rep. So in addition to the</p> <p>13 algorithms, every order was reviewed by customer</p> <p>14 service.</p> <p>15 BY MR. KO:</p> <p>16 Q. And how do you know that? Is that what</p> <p>17 you were told by counsel?</p> <p>18 MR. O'CONNOR: Objection. Instruct you</p> <p>19 not to answer what we discussed.</p> <p>20 BY MR. KO:</p> <p>21 Q. Earlier you said --</p> <p>22 MR. O'CONNOR: (Inaudible) privilege.</p> <p>23 BY MR. KO:</p> <p>24 Q. Earlier you said that you did not recall</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. And turning back to your testimony earlier</p> <p>2 just a moment ago, when you were saying the customer</p> <p>3 service reps would sometimes review the order.</p> <p>4 Do you know whether or not that review was</p> <p>5 ever documented in any way?</p> <p>6 A. I do not, but they reviewed every order.</p> <p>7 Q. And when you say they reviewed every</p> <p>8 order, are you saying that they reviewed every single</p> <p>9 order ever entered into between Mallinckrodt and a</p> <p>10 wholesaler distributor customer?</p> <p>11 A. I'm saying that they reviewed every one of</p> <p>12 these orders that had the peculiar order report.</p> <p>13 Q. I see. So outside of the peculiar order</p> <p>14 algorithm system, was there a separate system or</p> <p>15 protocol for a customer service rep to identify an</p> <p>16 order as being potentially peculiar?</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. Not that I'm aware of.</p> <p>19 BY MR. KO:</p> <p>20 Q. So in other words, the customer service</p> <p>21 rep or individual that would review an order is doing</p> <p>22 so only after it is identified as peculiar by a certain</p> <p>23 algorithm; is that accurate?</p> <p>24 MR. O'CONNOR: Objection to form.</p>
<p style="text-align: right;">Page 91</p> <p>1 ever seeing an SOM program prior to a certain time</p> <p>2 period. Is that accurate?</p> <p>3 MR. O'CONNOR: Objection. Form.</p> <p>4 A. I didn't recall seeing -- I believe the</p> <p>5 question was a written report, so I didn't recall</p> <p>6 seeing a written report.</p> <p>7 BY MR. KO:</p> <p>8 Q. So if you've never seen a written report,</p> <p>9 how did you gain an understanding of what the SOM</p> <p>10 program was like prior to when Mallinckrodt ever had a</p> <p>11 written report?</p> <p>12 A. So I was advised by another employee.</p> <p>13 Q. And which employee?</p> <p>14 A. Karen Harper.</p> <p>15 Q. And when did she advise you of that?</p> <p>16 A. January of this year.</p> <p>17 Q. So prior to January of 2019, did you ever</p> <p>18 have an understanding of what the SOM program was like</p> <p>19 prior to when Mallinckrodt had a written report -- or</p> <p>20 written policy? Excuse me.</p> <p>21 MR. O'CONNOR: Objection. Form.</p> <p>22 A. Outside of what she might have discussed</p> <p>23 with me in this e-mail, no.</p> <p>24 BY MR. KO:</p>	<p style="text-align: right;">Page 93</p> <p>1 A. That's my understanding.</p> <p>2 BY MR. KO:</p> <p>3 Q. And so earlier we had talked about a</p> <p>4 multitiered structure or a two-tiered structure, and we</p> <p>5 had identified or we had discussed the concept of first</p> <p>6 an order being triggered pursuant to an algorithm and</p> <p>7 then subsequently being identified as peculiar.</p> <p>8 Do you recall that discussion?</p> <p>9 A. Yes.</p> <p>10 Q. And after that review, then an order</p> <p>11 was -- or excuse me.</p> <p>12 After that report was created, the order</p> <p>13 would then be analyzed to determine whether or not it</p> <p>14 was suspicious; right?</p> <p>15 A. Correct.</p> <p>16 Q. And I'm just trying to get an</p> <p>17 understanding of when the customer service rep would</p> <p>18 review the order, and it would be after the order was</p> <p>19 identified as peculiar; correct?</p> <p>20 A. That's my understanding.</p> <p>21 Q. And they would not review -- just so the</p> <p>22 record is clear, they would not review every order</p> <p>23 prior to any identification of the order being</p> <p>24 peculiar; is that correct?</p>

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1 MR. O'CONNOR: Objection to form.
2 A. Correct.
3 BY MR. KO:
4 Q. And so going -- just looking back at this
5 document, the orders that appear here -- it's your
6 testimony that it's your belief these orders were
7 identified pursuant to whatever algorithm was in place
8 as of 2003; correct?
9 A. That's my understanding.
10 Q. And these orders then would not have been
11 identified through any other process other than the
12 peculiar order algorithm that was in place; correct?
13 A. Not that I'm aware of.
14 Q. You can set that aside. I'm going to hand
15 you a copy of what's going to be marked as Gillies
16 Exhibit --
17 MS. GAFFNEY: 6.
18 BY MR. KO:
19 Q. -- 6. And for the record, this is --
20 ends in Bates 7026341.
21 [Exhibit Mallinckrodt-Gillies-006
22 marked for identification.]
23 Q. And this is a letter from Eileen Spaulding
24 to Karen Harper dated April 24th, 2014, and you said

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1 earlier that Eileen is a member of the SOM team; is
2 that correct?
3 A. She is.
4 Q. And she's also a member of the DEA
5 compliance group?
6 A. She is.
7 Q. And similarly, Karen Harper is also a
8 member of the DEA compliance group and the SOM team?
9 A. Yes.
10 Q. And Eileen indicates to Karen that, quote,
11 I can recall having a suspicious order monitoring
12 system in place of some type with the start of
13 distribution activities from Hobart 2001, end quote.
14 Did I read that correctly?
15 A. Yes.
16 Q. So -- and let me continue. However, the
17 attached is the earliest SOM report that I have in my
18 e-mail system. At this time the reports were being
19 generated monthly. The attached report is for December
20 2013 orders that were reviewed.
21 And I believe she means to reference
22 December 2003, but we can go over that later. But did
23 I read that portion of the e-mail correctly?
24 A. Yes.

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1 MR. O'CONNOR: Objection.
2 BY MR. KO:
3 Q. So again, as of April 2014, Eileen, a
4 member of the SOM team, is identifying to Karen, also a
5 member of the SOM team, that the earliest SOM report
6 that Mallinckrodt has access to is as of 2003; is that
7 accurate?
8 MR. O'CONNOR: Objection to form.
9 A. I'm sorry. Could you restate that one
10 more time?
11 BY MR. KO:
12 Q. Sure. As of April 2014, Eileen, a member
13 of the SOM team, is identifying to Karen, also a member
14 of the SOM team, that the earliest SOM report that
15 Mallinckrodt had access to is as of 2003. Is that
16 accurate?
17 MR. O'CONNOR: Same objection.
18 A. She's saying the attached report is from
19 there.
20 BY MR. KO:
21 Q. Is there any reference to a SOM report
22 prior to 2003?
23 A. Not in this e-mail, no.
24 Q. And Ms. Spaulding also indicates that

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1 there -- she does recall having an SOM system in place
2 starting in 2001. Is that accurate?
3 A. Yes.
4 Q. And do you have any reason to dispute the
5 veracity of this e-mail?
6 A. No.
7 MR. O'CONNOR: Objection to form.
8 BY MR. KO:
9 Q. Have you seen any documents that suggest
10 an SOM system in place prior to 2001?
11 A. Not that I can recall.
12 Q. Have you seen any documents that indicate
13 an SOM report prior to 2003?
14 A. Not that I can recall.
15 Q. You can set that aside. Now, is it
16 accurate to state that Mallinckrodt made substantial
17 changes to its SOM policy between the 2008 to 2011 time
18 period?
19 MR. O'CONNOR: Objection to form.
20 A. We were always looking to enhance the
21 program.
22 BY MR. KO:
23 Q. So is it accurate to state that during
24 the 2008 through 2011 time period, Mallinckrodt made

<p style="text-align: right;">Page 98</p> <p>1 substantial revisions to its SOM program?</p> <p>2 MR. O'CONNOR: Objection to form.</p> <p>3 A. So there were changes made.</p> <p>4 BY MR. KO:</p> <p>5 Q. And would you agree with me that there</p> <p>6 were substantial changes?</p> <p>7 MR. O'CONNOR: Objection to form.</p> <p>8 A. I don't know that I would characterize it</p> <p>9 as substantial.</p> <p>10 BY MR. KO:</p> <p>11 Q. How would you characterize it?</p> <p>12 A. That there were changes made to the SOM</p> <p>13 program with the more experience that they had and the</p> <p>14 more information they got.</p> <p>15 Q. And the changes were made with the intent</p> <p>16 to improve and enhance the system, as you said;</p> <p>17 correct?</p> <p>18 A. Yeah, to enhance the system. Correct.</p> <p>19 Q. I'm going to hand you a copy of what's</p> <p>20 going to be marked as Gillies Exhibit 7.</p> <p>21 [Exhibit Mallinckrodt-Gillies-007</p> <p>22 marked for identification.]</p> <p>23 Q. And for the record, this is a document</p> <p>24 titled suspicious order monitoring team charter, with</p>	<p style="text-align: right;">Page 100</p> <p>1 document, this indicates, does it not, that the</p> <p>2 suspicious order monitoring team start date was March</p> <p>3 28th, 2008?</p> <p>4 A. That's what contained on that line, but</p> <p>5 later it says it's an upgrade to Mallinckrodt's</p> <p>6 existing SOM program, so if there's an existing SOM</p> <p>7 program, then there's got to be team members that are</p> <p>8 working on that program.</p> <p>9 Q. Well, I understand the difference</p> <p>10 between -- well, I understand your point about a</p> <p>11 program, but the fact that there is a program in place,</p> <p>12 does that necessarily mean that there was a team in</p> <p>13 place as well?</p> <p>14 A. Yes.</p> <p>15 Q. And have you seen any documents predating</p> <p>16 March 28th, 2008, that reflect an official team to the</p> <p>17 suspicious order monitoring system that Mallinckrodt</p> <p>18 had?</p> <p>19 MR. O'CONNOR: Objection to form.</p> <p>20 A. So there were team members.</p> <p>21 BY MR. KO:</p> <p>22 Q. So is it your testimony today that were</p> <p>23 team members of the suspicious order monitoring team</p> <p>24 prior to March 2008?</p>
<p style="text-align: right;">Page 99</p> <p>1 Bates ending in 496062.</p> <p>2 So I know earlier we had discussed whether</p> <p>3 or not you were aware of when Mallinckrodt first began</p> <p>4 its SOM team.</p> <p>5 Does this document accurately reflect that</p> <p>6 the SOM team began on March 28th of 2008?</p> <p>7 MR. O'CONNOR: Objection to form.</p> <p>8 A. I'm sorry. Could you repeat the question?</p> <p>9 I'm finished reading this document now.</p> <p>10 BY MR. KO:</p> <p>11 Q. Sure. Does this document accurately</p> <p>12 reflect that the SOM team began on March 28th, 2008?</p> <p>13 MR. O'CONNOR: Objection to form.</p> <p>14 A. No.</p> <p>15 BY MR. KO:</p> <p>16 Q. Have you -- at the very beginning of this</p> <p>17 document -- first of all, it's titled suspicious order</p> <p>18 monitoring team charter; is that accurate?</p> <p>19 A. Yes.</p> <p>20 Q. Do you recall -- is there a team charter</p> <p>21 in place currently for the SOM team?</p> <p>22 A. I don't know that there -- the procedure</p> <p>23 is called a charter or anything, so --</p> <p>24 Q. And with respect to this particular</p>	<p style="text-align: right;">Page 101</p> <p>1 A. Yes.</p> <p>2 Q. And who were they?</p> <p>3 A. I don't know the names of who was</p> <p>4 involved, but we had an algorithm system. We had the</p> <p>5 customer service reps. Karen Harper. DEA compliance</p> <p>6 was part of that SOM team.</p> <p>7 Q. And how do you know that there was --</p> <p>8 well, first of all, we've established that you haven't</p> <p>9 seen any documents that reflect an SOM team prior to</p> <p>10 March 2008; is that accurate?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. A document that lists team members?</p> <p>13 Correct.</p> <p>14 BY MR. KO:</p> <p>15 Q. And so how do you have knowledge regarding</p> <p>16 the composition of an SOM team prior to March of 2008?</p> <p>17 A. Because there was an SOM program.</p> <p>18 Q. Other than -- and you learned that there</p> <p>19 was an SOM program through your conversations with</p> <p>20 Karen Harper; is that accurate?</p> <p>21 A. Yes.</p> <p>22 Q. And you have not seen any documents</p> <p>23 reflecting an actual SOM program prior to 2008; is that</p> <p>24 accurate?</p>

<p style="text-align: right;">Page 102</p> <p>1 MR. O'CONNOR: Objection to form.</p> <p>2 A. No.</p> <p>3 BY MR. KO:</p> <p>4 Q. You have seen documents reflecting an SOM</p> <p>5 program prior to 2008?</p> <p>6 A. I mean, you just showed me a document that</p> <p>7 had a peculiar order report, and this came from the SOM</p> <p>8 program.</p> <p>9 Q. And separate and apart from whether or not</p> <p>10 there was an SOM report, did you review or have any</p> <p>11 understanding in the documents you reviewed in</p> <p>12 connection with this deposition of the team members</p> <p>13 that were part of that SOM program?</p> <p>14 A. No.</p> <p>15 Q. And do you have an understanding of</p> <p>16 whether or not there was any written policy governing</p> <p>17 the SOM program prior to 2008 at Mallinckrodt?</p> <p>18 MR. O'CONNOR: Objection to form.</p> <p>19 A. No.</p> <p>20 BY MR. KO:</p> <p>21 Q. So at least we can agree, for purposes of</p> <p>22 this document, it indicates that the team's start date</p> <p>23 for this particular suspicious order monitoring team is</p> <p>24 as of March 2008; is that accurate?</p>	<p style="text-align: right;">Page 104</p> <p>1 referring to this team as outlined in this charter?</p> <p>2 A. Yeah, I believe that was your earlier</p> <p>3 question, to clarify that we had a team previous to</p> <p>4 this based on the SOM program. So from this team.</p> <p>5 Q. Separate and apart from this document --</p> <p>6 let's pretend that the document doesn't exist -- how</p> <p>7 long was Ms. Harper the team leader of the suspicious</p> <p>8 order monitoring program team at Mallinckrodt?</p> <p>9 MR. O'CONNOR: Objection to form.</p> <p>10 A. So I don't know all the dates. I'm sorry.</p> <p>11 BY MR. KO:</p> <p>12 Q. Do you know -- do you have any</p> <p>13 understanding of whether or not she was the team leader</p> <p>14 prior to 2008?</p> <p>15 MR. O'CONNOR: Objection to form.</p> <p>16 A. Yes.</p> <p>17 BY MR. KO:</p> <p>18 Q. And how did you gain that understanding?</p> <p>19 A. From Karen.</p> <p>20 Q. And did she tell you how long she was the</p> <p>21 team leader prior to 2008?</p> <p>22 A. She did not.</p> <p>23 Q. And how about after 2011? Did you have</p> <p>24 any conversations with her about how long she was a</p>
<p style="text-align: right;">Page 103</p> <p>1 A. For this particular team, yes.</p> <p>2 Q. And the team leader is Karen Harper; is</p> <p>3 that accurate?</p> <p>4 A. That's what this document says.</p> <p>5 Q. And is it your -- has Karen Harper always</p> <p>6 been the team leader of the suspicious order monitoring</p> <p>7 team at Mallinckrodt?</p> <p>8 MR. O'CONNOR: Objection to form.</p> <p>9 A. No.</p> <p>10 BY MR. KO:</p> <p>11 Q. And during what periods of time was she</p> <p>12 the team leader of the SOM team?</p> <p>13 A. So on this team, from that date until 2011</p> <p>14 time frame.</p> <p>15 Q. So the record is clear, your testimony is</p> <p>16 that Karen Harper was the team leader of the SOM</p> <p>17 program from approximately March of 2008 to 2011?</p> <p>18 A. For this team. Some of the members could</p> <p>19 have changed through that time, though.</p> <p>20 Q. Was there another suspicious order</p> <p>21 monitoring team between the 2008 and 2011 time period?</p> <p>22 A. Not that I'm aware of.</p> <p>23 Q. So I'm just trying to get an</p> <p>24 understanding. When you say of this team, you're</p>	<p style="text-align: right;">Page 105</p> <p>1 team leader of the SOM team after 2011?</p> <p>2 A. I did not.</p> <p>3 Q. Who is the team leader currently of the --</p> <p>4 of Mallinckrodt's SOM program?</p> <p>5 MR. O'CONNOR: Objection to form.</p> <p>6 A. Don Lohman.</p> <p>7 BY MR. KO:</p> <p>8 Q. And how long has he been the team leader?</p> <p>9 A. Since sometime in 2011.</p> <p>10 Q. And was Ms. Harper -- did she continue to</p> <p>11 be a member of the SOM team after 2011?</p> <p>12 A. Yes.</p> <p>13 Q. And you can actually set that document</p> <p>14 aside. I'm going to hand you a copy of what will be</p> <p>15 marked as Gillies Exhibit 8.</p> <p>16 MS. GAFFNEY: 8.</p> <p>17 [Exhibit Mallinckrodt-Gillies-008</p> <p>18 marked for identification.]</p> <p>19 BY MR. KO:</p> <p>20 Q. And for the record, this ends in Bates</p> <p>21 7053963. And this also reflects some notes from a</p> <p>22 Hobart meeting with DEA Albany on SOM and quota between</p> <p>23 DEA and Mallinckrodt.</p> <p>24 And Mr. Gillies, I'm happy to allow you to</p>

<p style="text-align: right;">Page 106</p> <p>1 review other portions of this document if you'd like, 2 but I just want to direct you to certain portions of 3 it. 4 First of all, at the top of this e-mail 5 there's a list of people who attended this meeting at 6 both Mallinckrodt and DEA; is that accurate? 7 A. Yes. 8 Q. And both Mr. Lohman and Ms. Harper were in 9 attendance? 10 A. That's what this states. 11 Q. As well as Ms. Spaulding? 12 A. Yes. 13 Q. Now, I want to go down to the portion of 14 these notes at the bottom of the first page regarding 15 SOM. Do you see that? 16 A. Yes. 17 Q. And it appears that Mr. Lohman had some 18 interactions with the DEA regarding Mallinckrodt's SOM 19 program; is that fair? 20 A. Yes. 21 Q. And turning to Page 2 of these notes, 22 there was a question apparently asked by the DEA, how 23 many orders have been deemed suspicious? Do you see 24 that?</p>	<p style="text-align: right;">Page 108</p> <p>1 that accurate to say? 2 MR. O'CONNOR: Objection to form. 3 A. I don't know. 4 BY MR. KO: 5 Q. You have no recollection of what -- well, 6 strike that. 7 So it's your understanding that there was 8 an update to the SOM program in March of 2012; 9 accurate? 10 A. Yes. 11 Q. Do you have under -- any understanding of 12 what provisions of the SOM program were updated during 13 that time? 14 A. There was an algorithm change. 15 Q. And what did that algorithm change consist 16 of? 17 A. I believe the algorithm had a [REDACTED], and it 18 was updated to a [REDACTED]. 19 Q. And when you say [REDACTED], can you please 20 describe to the court -- [REDACTED] relative to what? 21 A. I cannot recall. 22 Q. Let's actually set this document aside. 23 And I'll hand you a copy of what's previously marked as 24 Stewart Exhibit 1.</p>
<p style="text-align: right;">Page 107</p> <p>1 A. Yes. 2 Q. And the answer that either Mr. Lohman or 3 someone in attendance at Mallinckrodt gave was none. 4 It was explained that this updated SOM program went 5 into place on 3-1-12 and no orders have been determined 6 to be suspicious since that time. 7 Did I read that correctly? 8 A. Yes. 9 Q. Is it accurate to state then that the 10 updated SOM program did not become effective at 11 Mallinckrodt until March 1st, 2012, according to this 12 document? 13 MR. O'CONNOR: Objection to form. 14 A. I mean, without reading this whole 15 document, I'm not sure that's what that says, but -- 16 BY MR. KO: 17 Q. Okay. And let me just ask you. Do you 18 have an understanding of whether or not the SOM program 19 was updated in March of 2012? 20 A. There was an update during that time 21 frame. 22 Q. And that update, among other things, 23 changed the structure from a peculiar order 24 classification to an unusual order classification; is</p>	<p style="text-align: right;">Page 109</p> <p>1 A. Okay. 2 Q. Which for the record, it ends in Bates 3 299558. This is a short e-mail exchange, so go ahead 4 and take a look at it. 5 A. Okay. 6 Q. Let me know when you're done. 7 A. Okay. 8 Q. So this e-mail exchange dated April 1st, 9 2008, involves, among others, Karen Harper, Jim Rausch, 10 and Bill Ratliff; is that correct? 11 A. Yes. 12 Q. And who was Jim Rausch? 13 A. He was one of the customer service reps. 14 Q. And did he have responsibilities with 15 respect to Mallinckrodt's SOM program? 16 A. Yes. 17 Q. And what were those responsibilities? 18 A. He was reviewing the orders. 19 Q. And was he reviewing -- when you say 20 orders, is he reviewing peculiar orders in particular? 21 A. Yes. 22 Q. And peculiar orders that are triggered 23 under the then-existing algorithm utilized by 24 Mallinckrodt; correct?</p>

<p style="text-align: right;">Page 110</p> <p>1 A. Correct.</p> <p>2 Q. Bill Ratliff is also mentioned here. Who</p> <p>3 is he?</p> <p>4 A. He was the former head of security for</p> <p>5 Mallinckrodt.</p> <p>6 Q. And what responsibilities did he have with</p> <p>7 respect to the SOM program?</p> <p>8 A. He was part of the SOM team.</p> <p>9 Q. And what were his responsibilities?</p> <p>10 A. I can't recall.</p> <p>11 Q. And do you know how long he was a member</p> <p>12 of the SOM team?</p> <p>13 A. While he was employed.</p> <p>14 Q. While he was employed at Mallinckrodt?</p> <p>15 A. Yeah. But I do not know what his start</p> <p>16 date was at Mallinckrodt.</p> <p>17 Q. Is it your understanding that he was a</p> <p>18 member of the SOM team throughout the duration of his</p> <p>19 employment?</p> <p>20 A. That's my understanding.</p> <p>21 Q. And what about Mr. Rausch? How long was</p> <p>22 he part of the SOM team?</p> <p>23 A. I do not know what his dates were.</p> <p>24 Q. Now, we can go over some of the details of</p>	<p style="text-align: right;">Page 112</p> <p>1 hired by Mallinckrodt, former DEA employee.</p> <p>2 Q. And was he an outside contractor retained</p> <p>3 to advise specifically on SOM obligations?</p> <p>4 A. Yes.</p> <p>5 Q. And I believe he was also retained to</p> <p>6 advise on other Mallinckrodt DEA obligations such as</p> <p>7 any responsibilities with respect to quota. Is that</p> <p>8 accurate?</p> <p>9 A. I don't know that.</p> <p>10 Q. Now, Mr. Ratliff indicates that as of</p> <p>11 April 1st, 2008, there is a need to strengthen</p> <p>12 Mallinckrodt's suspicious order identification system.</p> <p>13 Do you see that?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. That's what you've highlighted there, that</p> <p>16 they had the conference call with Sapienza to</p> <p>17 strengthen the system.</p> <p>18 BY MR. KO:</p> <p>19 Q. So is it accurate to state that as of</p> <p>20 April of 2008, individuals within the SOM team at</p> <p>21 Mallinckrodt felt the need to strengthen Mallinckrodt's</p> <p>22 suspicious order monitoring program?</p> <p>23 MR. O'CONNOR: Objection to form.</p> <p>24 A. I think the team was always looking to</p>
<p style="text-align: right;">Page 111</p> <p>1 this e-mail if you'd like, but is this -- is it</p> <p>2 accurate to state that this is an e-mail that reflects</p> <p>3 the practice we were describing a moment ago or earlier</p> <p>4 today regarding Mallinckrodt sending monthly reports to</p> <p>5 DEA?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. That's how I understand this reference.</p> <p>8 BY MR. KO:</p> <p>9 Q. In other words, as of April of 2008,</p> <p>10 Mallinckrodt, and in particular Jim Rausch, is sending</p> <p>11 monthly peculiar order reports to DEA; is that correct?</p> <p>12 A. Yes.</p> <p>13 Q. And the DEA tells Mr. Ratliff and</p> <p>14 Mallinckrodt to stop sending those letters; correct?</p> <p>15 A. That's what referenced in here, yes.</p> <p>16 Q. And in the second paragraph of this</p> <p>17 e-mail, Mr. Ratliff indicates I advised that we have a</p> <p>18 conference call planned with Frank Sapienza on Friday</p> <p>19 to strengthen our suspicious order identification</p> <p>20 system, end quote.</p> <p>21 Did I read that correctly?</p> <p>22 A. Yes.</p> <p>23 Q. First of all, who's Frank Sapienza?</p> <p>24 A. He was an outside contractor that was</p>	<p style="text-align: right;">Page 113</p> <p>1 enhance the program.</p> <p>2 BY MR. KO:</p> <p>3 Q. And is it accurate to state that as of</p> <p>4 April 2008, individuals in the SOM team specifically</p> <p>5 felt the need to strengthen Mallinckrodt's suspicious</p> <p>6 order monitoring program?</p> <p>7 MR. O'CONNOR: Objection to form. Asked</p> <p>8 and answered.</p> <p>9 A. Yes.</p> <p>10 BY MR. KO:</p> <p>11 Q. Now, do you have any understanding of</p> <p>12 whether or not Mallinckrodt resumed -- well, strike</p> <p>13 that.</p> <p>14 Once Mallinckrodt stopped sending monthly</p> <p>15 reports to DEA, was there any communications with the</p> <p>16 DEA that Mallinckrodt had regarding which orders were</p> <p>17 either peculiar or suspicious?</p> <p>18 MR. O'CONNOR: Objection to form.</p> <p>19 A. Possibly.</p> <p>20 BY MR. KO:</p> <p>21 Q. Do you recall seeing any documentation or</p> <p>22 did you talk with anyone regarding any type of reports</p> <p>23 that Mallinckrodt sent following its decision to stop</p> <p>24 sending monthly reports to the DEA in April of 2008?</p>

<p style="text-align: right;">Page 114</p> <p>1 A. So my understanding is that it was April 2 of 2008 that we stopped sending them, not October that 3 was referenced in this previous document you showed me. 4 And then in 2012, we started sending reports to the DEA 5 again. 6 Q. So that's helpful. So there was a period 7 of time in which reports were not sent to the DEA; is 8 that accurate? 9 A. Yes. 10 Q. And that period of time was from mid-2008 11 through 2012; correct? 12 A. From April 2008 till some time in 2012. 13 Q. And do you have a general understanding of 14 when in 2012 that practice resumed? 15 A. I don't. 16 Q. And in 2012, what did those reports 17 consist of? 18 A. I don't recall. But I believe we've given 19 those reports to you guys. So I just don't recall what 20 they were. 21 Q. And when you say given those reports to 22 you guys, you mean that your counsel has produced those 23 documents in this litigation? 24 A. Yes. Sorry.</p>	<p style="text-align: right;">Page 116</p> <p>1 excessive order reports to the DEA; correct? 2 A. Whatever that time frame is from April of 3 2008 to 2012, yes. 4 Q. So there was -- during that time period, 5 Mallinckrodt did not send any type of monthly excessive 6 order report to DEA; correct? 7 A. Correct. 8 Q. And when Mallinckrodt began to send 9 monthly reports again to the DEA, what happened that -- 10 or what happened to reflect the understanding that 11 Mallinckrodt would then be resuming delivery of 12 order -- monthly order reports to DEA? 13 MR. O'CONNOR: Objection to form. 14 A. So there's a privilege here. 15 MR. O'CONNOR: In that case, I would 16 object and instruct the witness not to answer to the 17 extent it would require revealing communications with 18 counsel on the basis of attorney-client privilege. 19 BY MR. KO: 20 Q. So is your complete answer covered by the 21 privilege? 22 A. On this question, yes. 23 Q. So during the 2012 time period when 24 Mallinckrodt began resuming sending reports to the DEA,</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. That's okay. And were those -- strike 2 that. 3 Do you have any understanding of why there 4 was -- why Mallinckrodt decided not to send any reports 5 to DEA during that approximate three-and-a-half-year 6 time period? 7 MR. O'CONNOR: Objection to form. 8 A. So this would have been in response to the 9 December 2007 letter where DEA advised stop sending the 10 reports. 11 BY MR. KO: 12 Q. But eventually Mallinckrodt resumed their 13 practice of sending some sort of report to DEA, as you 14 said, in 2012; right? 15 A. That's correct. 16 Q. So what was it about those reports that 17 satisfied Mallinckrodt sufficient enough to send 18 letters again to the DEA? Or reports. Strike that. 19 MR. O'CONNOR: Objection to form. 20 BY MR. KO: 21 Q. Let me make sure the record is -- poor 22 question. Let me ask it again. 23 There was a three-and-a-half-year time 24 period in which Mallinckrodt did not send monthly</p>	<p style="text-align: right;">Page 117</p> <p>1 was that when you were part of -- was that after you 2 joined Mallinckrodt? 3 A. It either started right before I joined or 4 right after I joined. 5 Q. So then it's safe to say approximately in 6 the summer of 2012 was when Mallinckrodt resumed 7 sending monthly reports to DEA? 8 A. That's my understanding. 9 Q. And -- but you don't know what those 10 reports consist of? 11 A. It wasn't part of my role on the SOM team, 12 so no, I don't recall what they consist of. 13 Q. And separate and apart from your role on 14 the SOM team, you didn't review any of those reports or 15 gain an understanding of what those reports consisted 16 of in preparation for your deposition today? 17 A. Again, I believe I was shown the 18 documents, but I just can't recall. 19 Q. And when you say you were shown the 20 documents, what documents were you specifically shown 21 in this context? 22 A. Would have been copies of these reports. 23 Q. And you have no recollection of what those 24 reports consisted of right now?</p>

<p style="text-align: right;">Page 118</p> <p>1 A. I do not.</p> <p>2 Q. Yeah, you can set that aside. Thank you.</p> <p>3 A. Okay.</p> <p>4 Q. Sorry. Bear with us. Some technical</p> <p>5 difficulties.</p> <p>6 A. That's all right.</p> <p>7 [Exhibit Mallinckrodt-Gillies-010</p> <p>8 marked for identification.]</p> <p>9 Q. I'm going to hand you a copy of what's</p> <p>10 going to be marked as Gillies Exhibit 10. And for the</p> <p>11 record, this is an April 8th, 2008, e-mail between</p> <p>12 Karen Harper and Bill Ratliff ending in Bates 273892</p> <p>13 with an attachment.</p> <p>14 So earlier today we were discussing</p> <p>15 whether or not Mallinckrodt had written policies</p> <p>16 governing its SOM program.</p> <p>17 Do you recall that?</p> <p>18 A. Yes.</p> <p>19 Q. And you said that you had no recollection</p> <p>20 of when or whether you've seen any of the written</p> <p>21 policies with respect to its SOM program.</p> <p>22 Do you recall that?</p> <p>23 A. Prior to a certain date, was your</p> <p>24 question, so --</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. And the first -- one of the documents that</p> <p>2 she is referencing is in fact this SOM compliance</p> <p>3 procedure policy; correct?</p> <p>4 A. This controlled substance SOM procedure?</p> <p>5 Q. Yes, the attachment.</p> <p>6 A. Yes. Okay. Yeah.</p> <p>7 Q. So is it accurate to say -- well, let's</p> <p>8 take a step back.</p> <p>9 You had indicated earlier that you had</p> <p>10 reviewed certain documents in preparation for this</p> <p>11 deposition today and that you had seen some written</p> <p>12 policies; correct?</p> <p>13 A. Yes.</p> <p>14 Q. Did you review this written policy?</p> <p>15 A. No.</p> <p>16 Q. You did not? Okay. Is it accurate --</p> <p>17 regardless of whether or not you reviewed this</p> <p>18 particular one, is it accurate to state that this is a</p> <p>19 draft of Mallinckrodt's SOM policy?</p> <p>20 A. That's what it appears to be, a draft.</p> <p>21 Q. And this draft is dated -- well, this</p> <p>22 draft doesn't have a date, but it's circulated on April</p> <p>23 1st, 2008; correct?</p> <p>24 A. The date on the e-mail is April -- is that</p>
<p style="text-align: right;">Page 119</p> <p>1 Q. Right. And is that -- so this document</p> <p>2 reflects, as I alluded to earlier, an e-mail from Ms.</p> <p>3 Harper to Mr. Ratliff attaching an SOM draft policy; is</p> <p>4 that accurate to say?</p> <p>5 A. I'm sorry. Can I have a moment to read</p> <p>6 this?</p> <p>7 Q. Sure.</p> <p>8 A. Okay. I'm sorry. Go ahead.</p> <p>9 Q. Does the attachment contained in this</p> <p>10 exhibit -- the attachment that is titled DEA compliance</p> <p>11 procedure, controlled substance suspicious order</p> <p>12 monitoring -- does this reflect a draft SOM policy of</p> <p>13 Mallinckrodt?</p> <p>14 A. Yes.</p> <p>15 Q. And in the cover e-mail, there is a</p> <p>16 reference from Ms. Harper to Mr. Ratliff that she's</p> <p>17 attaching it for his review; correct?</p> <p>18 A. Yes.</p> <p>19 Q. And that she's making a start or she's</p> <p>20 making a first pass at a certain document. Is that</p> <p>21 accurate?</p> <p>22 MR. O'CONNOR: Objection to form.</p> <p>23 A. Yes.</p> <p>24 BY MR. KO:</p>	<p style="text-align: right;">Page 121</p> <p>1 6th or 8th?</p> <p>2 Q. Yeah, I believe it's April 8th. So --</p> <p>3 A. Okay.</p> <p>4 Q. Thank you for that clarification. So this</p> <p>5 first draft of Mallinckrodt's SOM program is circulated</p> <p>6 as of April 8th, 2008; correct?</p> <p>7 A. Yes.</p> <p>8 Q. And in this particular draft policy, you</p> <p>9 see the reference to peculiar order and suspicious</p> <p>10 order?</p> <p>11 A. Yes.</p> <p>12 Q. And is there any indication in this</p> <p>13 particular draft regarding any algorithm of how a</p> <p>14 peculiar order is determined by Mallinckrodt?</p> <p>15 A. Can you restate that, or repeat the</p> <p>16 question?</p> <p>17 Q. Sure. Sure. I'll actually rephrase the</p> <p>18 question.</p> <p>19 As of April 8th, 2008, is it accurate to</p> <p>20 say that Mallinckrodt did not memorialize a particular</p> <p>21 algorithm for purposes of defining a peculiar order?</p> <p>22 MR. O'CONNOR: Objection to form.</p> <p>23 A. Not in this document.</p> <p>24 BY MR. KO:</p>

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1 Q. And do you have any understanding of
2 whether or not a peculiar order algorithm was
3 memorialized in any way outside of this document as of
4 April of 2008?
5 MR. O'CONNOR: Objection to form.
6 A. I know there was an algorithm, but I'm
7 unaware of any report.
8 BY MR. KO:
9 Q. In other words, just so the record is
10 clear, as far as you know, as of April of 2008 there
11 was no separate document that governed the definition
12 of what constitutes a peculiar order?
13 MR. O'CONNOR: Objection to form.
14 A. Okay -- that was a different question that
15 you just asked me. So I have no recollection of that.
16 BY MR. KO:
17 Q. And for purposes of this document, there's
18 no algorithm that's set forth in terms of what
19 constitutes a peculiar order; correct?
20 A. Not in this document.
21 Q. And there -- as far as you know, you've
22 not reviewed any other documents during this time
23 period that reflect a written policy memorializing what
24 constitutes a peculiar order; is that accurate?

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1 MR. O'CONNOR: Objection to form.
2 A. Not that I can recall.
3 BY MR. KO:
4 Q. And other than this draft SOM policy,
5 would Mallinckrodt have any other type of written
6 document that would define the algorithm used for
7 defining a peculiar order?
8 A. I don't know the answer to that question.
9 Q. Now, at the top of this page, in the top
10 right-hand corner there's an indication of effective
11 date and supersede date, and in fact, on top of that,
12 revision.
13 Do you see those?
14 A. Yes.
15 Q. And as we discussed earlier, there's no
16 effective date for this because it's a draft, among
17 other reasons, but do you see where it says Revision
18 Number 1?
19 A. Yes.
20 Q. So would it be fair to say that this is
21 the SOM team's first pass at a written SOM policy?
22 MR. O'CONNOR: Objection to form.
23 A. Yes.
24 BY MR. KO:

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1 Q. And with respect to the supersedes date,
2 there's no document that this particular draft is
3 superseding, so that also indicates that this is
4 Mallinckrodt's first pass at a written SOM policy;
5 correct?
6 A. It says no.
7 Q. Okay. Great. You can set that aside.
8 MR. O'CONNOR: Counsel, can we take a
9 short break and then --
10 MR. KO: Sure.
11 MR. O'CONNOR: It's been about an hour,
12 and then do lunch --
13 MR. KO: Sure. That's fine.
14 MR. O'CONNOR: -- after a short break?
15 MR. KO: Okay.
16 THE VIDEOGRAPHER: We are going off the
17 record at 11:46 AM.
18 [A brief recess was taken.]
19 THE VIDEOGRAPHER: We are back on the
20 record at 11:59 AM.
21 BY MR. KO:
22 Q. Welcome back from the break. In front of
23 you you have what has previously been marked as Stewart
24 Exhibit 13, which I'll represent for the record is

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1 titled DEA compliance procedure, controlled substance
2 suspicious order monitoring, ending in Bates 268911.
3 So feel free to look through this if you'd
4 like in detail, but I just have a few questions about
5 this that hopefully you can answer without going
6 through all the doc -- or throughout all the language
7 in it. But again, feel free to go ahead if you need
8 to.
9 So this -- the date of this is May 13th,
10 2008; correct?
11 A. Yes.
12 Q. And this appears to be a Draft 2; is that
13 accurate?
14 A. That's what it says -- Draft 2.
15 Q. And did you review this particular draft
16 written policy in connection with preparing for this
17 deposition today?
18 A. No.
19 Q. And for this particular draft there is --
20 consistent with the one that we just looked at from
21 April, there are definitions of peculiar orders and
22 suspicious orders. Do you see that?
23 A. Yes.
24 Q. And as far as the peculiar order is

<p style="text-align: right;">Page 126</p> <p>1 defined, there's no indication of an algorithm in that 2 particular definition; is that accurate? 3 A. It doesn't say algorithm, but meets an 4 internal established criteria. 5 Q. Is there any indication in this document 6 of an algorithm or a specific algorithm that 7 Mallinckrodt is utilizing for purposes of defining a 8 peculiar order? 9 MR. O'CONNOR: Objection to form. 10 A. No mention of algorithm. 11 BY MR. KO: 12 Q. So is it accurate to say that as of May 13 13th, 2008, there was no algorithm that is mentioned at 14 least for purposes of the draft SOM policy? 15 MR. O'CONNOR: Objection to form. 16 A. It's not mentioned in this document. 17 BY MR. KO: 18 Q. And turning to the last page of this 19 document that I believe you were just at, there is a -- 20 there's an indication that the security director and 21 DEA compliance should be responsible for maintaining a 22 file for record retention of suspicious order 23 monitoring documents and reports. 24 Do you see that portion of the draft</p>	<p style="text-align: right;">Page 128</p> <p>1 period that covers? 2 A. I know it was in the material that I 3 reviewed, but I don't recall. 4 Q. Do you have an understanding of whether or 5 not Mallinckrodt had any kind of formal documentation 6 or record retention policy with respect to SOM 7 documents and reports during the 2008 to 2011 time 8 period? 9 MR. O'CONNOR: Objection to form. 10 A. My recollection is yes. 11 BY MR. KO: 12 Q. And what is that recollection based on? 13 A. Based on the -- what I learned preparing 14 for this deposition. 15 Q. And that -- and what you learned was 16 through review of certain documents that reflected SOM 17 documents and reports; is that accurate to say? 18 A. Yes. 19 Q. And I'm just trying to get an 20 understanding of what that specifically consisted of, 21 because you're telling me that you reviewed certain 22 things. 23 So what did you review? 24 MR. O'CONNOR: Objection to form, and to</p>
<p style="text-align: right;">Page 127</p> <p>1 policy? 2 A. Yes. 3 Q. And do you have any understanding of 4 whether or not Mallinckrodt did in fact keep some sort 5 of file for record retention of SOM documents and 6 reports? 7 A. Yes. 8 Q. And in what type of -- what type of 9 retention policy did Mallinckrodt utilize to maintain 10 these types of documents and reports? 11 A. I don't recall. 12 Q. So -- well, I'm having trouble 13 understanding. So you believe that Mallinckrodt 14 maintains a record retention policy with respect to SOM 15 documents and reports, but you don't know -- well, 16 strike that. Let's take it one at a time. 17 So Mallinckrodt -- it's your understanding 18 that Mallinckrodt maintains a record retention policy 19 with respect to SOM documents and reports? 20 A. Yes. 21 Q. And how do you know that? 22 A. I believe we provided you guys in this 23 matter a number of these documents. 24 Q. Do you have any understanding of what time</p>	<p style="text-align: right;">Page 129</p> <p>1 the extent we're talking about the collection of 2 documents that were selected by counsel for his review, 3 I'm going to instruct him not to answer. We've been 4 pretty indulgent on individuals, but we're not getting 5 into the full selection of documents. 6 BY MR. KO: 7 Q. Do you want me to repeat my question or 8 rephrase? 9 MR. O'CONNOR: Do you want to ask a more 10 tailored question? 11 MR. KO: Sure. 12 MR. O'CONNOR: Because otherwise he's 13 standing -- 14 MR. KO: Sure. 15 BY MR. KO: 16 Q. What documents did you review to help 17 inform you that Mallinckrodt had a formal document 18 retention policy with respect to its SOM documents and 19 records from the 2008 through 2011 time period? 20 MR. O'CONNOR: You can answer at a high 21 level. 22 A. Okay. There were documents provided to me 23 in preparation for providing this deposition. 24 BY MR. KO:</p>

<p style="text-align: right;">Page 130</p> <p>1 Q. Yeah, I understand the documents were 2 provided to you, and I'm asking you which documents did 3 you review to help inform you that Mallinckrodt had a 4 formal documentation or document retention policy with 5 respect to its SOM program in the 2008 through 2011 6 time period? 7 A. So there were e-mails and policies, 8 procedures, and a list of documents that were provided 9 to you in this matter. 10 Q. And which -- let's take the policies and 11 procedures. Which policies and procedures are you 12 referring to? 13 A. I don't recall. 14 Q. And let's take the e-mails. Which 15 e-mails -- were there e-mails that actually indicated 16 that there was a formal document retention policy with 17 respect to SOM records and documents from the 2008 and 18 2011 time period? 19 A. I -- 20 MR. O'CONNOR: Again, I'm going to object. 21 We're not going to get into individual document by 22 document everything he reviewed. 23 MR. KO: I understand that. 24 MR. O'CONNOR: I'll instruct the witness</p>	<p style="text-align: right;">Page 132</p> <p>1 very high level. 2 A. My recollection was it was just the 3 categories of documents that were provided to you guys 4 from the peculiar order reports. 5 BY MR. KO: 6 Q. Other than -- 7 A. And there were other documents, too, that 8 were provided to you guys that I reviewed. 9 Q. But to be clear, did any of these 10 documents that you review suggest that Mallinckrodt had 11 some sort of formal document or retention policy with 12 respect to Mallinckrodt SOM reports or documents during 13 the 2008-2011 time period? 14 A. I don't recall -- 15 MR. O'CONNOR: Objection to form. 16 A. I don't recall a document that says that. 17 BY MR. KO: 18 Q. You can set that one aside. 19 [Exhibit Mallinckrodt-Gillies-009 20 marked for identification.] 21 Q. I'm going to hand you a copy of what's -- 22 we're going a little bit out of order, but this is 23 Gillies Exhibit 9. And for the record, this ends in 24 Bates 419993.</p>
<p style="text-align: right;">Page 131</p> <p>1 not to answer on the basis of attorney-client 2 privilege. 3 BY MR. KO: 4 Q. So were there -- without discussing the 5 details of the specific e-mails, is it your testimony 6 that you reviewed e-mails that suggested that 7 Mallinckrodt had a formal document retention policy 8 with respect to SOM documents and reports in the 2008 9 and 2011 time period? 10 A. I don't recall that. 11 Q. So you don't recall seeing any e-mails 12 that reflect -- so just so the record is clear, yes or 13 no, do you recall reviewing e-mails from the 2008 and 14 2011 time period that reflect a document retention 15 policy with respect to SOM documents and records? 16 A. No. 17 Q. And then just the last part of your 18 answer, you said that you reviewed certain e-mails and 19 policies and procedures and other documents provided to 20 our side. 21 Can you generally describe what that third 22 category consisted of without getting into the details 23 of what was selected by counsel? 24 MR. O'CONNOR: Again, you can respond at a</p>	<p style="text-align: right;">Page 133</p> <p>1 And so Mr. Gillies, is it accurate to say 2 that this document reflects a Draft 3 published June 3 2nd, 2008, of Mallinckrodt's SOM policy? 4 A. Yes. 5 Q. And similar to the question I asked with 6 respect to the prior Draft 2 from May. In the peculiar 7 order definition, there's no indication of an algorithm 8 that Mallinckrodt is utilizing to define a peculiar 9 order; is that correct? 10 A. Again, I'd have to go through this to make 11 sure there's no reference to that. 12 Q. Sure. Well, let me just ask you a narrow 13 question. 14 A. Okay. 15 Q. On the definitions page at the bottom of 16 the first page. 17 A. Okay, I'm sorry. 18 Q. The definition appears to be similar to 19 the previous two drafts we reviewed; correct? 20 A. Yes. 21 Q. And in that particular definition of a 22 peculiar order, there's no reference to what the 23 algorithm Mallinckrodt would utilize to define a 24 peculiar order; correct?</p>

<p style="text-align: right;">Page 134</p> <p>1 A. Correct. Correct.</p> <p>2 Q. Now, going back to the top of this e-mail,</p> <p>3 in the purpose section, the second sentence states,</p> <p>4 quote, DEA cannot, will not tell a DEA registrant if an</p> <p>5 order is legitimate and/or if an order should be</p> <p>6 shipped.</p> <p>7 Did I read that correctly?</p> <p>8 A. Yes.</p> <p>9 Q. And it continues to say it is fundamental</p> <p>10 for sound operations that DEA registrants take</p> <p>11 reasonable measures to identify their customers,</p> <p>12 understand the normal and expected transactions</p> <p>13 typically conducted by those customer, and consequently</p> <p>14 identify those transactions that are suspicious in</p> <p>15 nature.</p> <p>16 Did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. Now, with respect to that second -- or the</p> <p>19 last sentence that I just read, is it accurate to say</p> <p>20 that Mallinckrodt has memorialized in this particular</p> <p>21 draft the understanding that it should know their</p> <p>22 customers in connection with implementing an SOM</p> <p>23 program?</p> <p>24 MR. O'CONNOR: Objection to form.</p>	<p style="text-align: right;">Page 136</p> <p>1 Q. And the portion of this policy that states</p> <p>2 that it is fundamental for the DEA registrant to</p> <p>3 understand the normal and expected transactions</p> <p>4 typically conducted by those customer -- what is your</p> <p>5 understanding of what those transactions consist of?</p> <p>6 A. So I --</p> <p>7 MR. O'CONNOR: Objection to form.</p> <p>8 A. I interpret this between Mallinckrodt and</p> <p>9 the customer.</p> <p>10 BY MR. KO:</p> <p>11 Q. So is it your understanding that the,</p> <p>12 quote, normal and expected transactions, end quote, are</p> <p>13 transactions between Mallinckrodt and its customers?</p> <p>14 A. That's how I read this.</p> <p>15 Q. And so in order -- is it your testimony</p> <p>16 then that Mallinckrodt's suspicious order monitoring</p> <p>17 system was only designed to identify the orders that</p> <p>18 were suspicious as between Mallinckrodt and its</p> <p>19 distributors?</p> <p>20 MR. O'CONNOR: Objection to form.</p> <p>21 A. That's what the regulation is, yes.</p> <p>22 BY MR. KO:</p> <p>23 Q. And do you believe that -- well, let's</p> <p>24 fast-forward to today's version of Mallinckrodt's SOM</p>
<p style="text-align: right;">Page 135</p> <p>1 A. Yes.</p> <p>2 BY MR. KO:</p> <p>3 Q. And would you also agree with me that this</p> <p>4 particular language reflects an understanding by</p> <p>5 Mallinckrodt that they would need to know their</p> <p>6 customers' transactions that they enter into as well;</p> <p>7 correct?</p> <p>8 MR. O'CONNOR: Objection to form.</p> <p>9 A. It says identify those transactions that</p> <p>10 are suspicious in nature.</p> <p>11 BY MR. KO:</p> <p>12 Q. And so would you agree with me that this</p> <p>13 language reflects an understanding by Mallinckrodt that</p> <p>14 they would need to know the details of the customers'</p> <p>15 transactions regarding Mallinckrodt opioids?</p> <p>16 MR. O'CONNOR: Objection to form.</p> <p>17 A. Between Mallinckrodt and the customer?</p> <p>18 BY MR. KO:</p> <p>19 Q. No, between Mallinckrodt's customer and a</p> <p>20 pharmacy and/or clinic that the wholesale distributor</p> <p>21 is dealing with.</p> <p>22 MR. O'CONNOR: Same objection.</p> <p>23 A. No.</p> <p>24 BY MR. KO:</p>	<p style="text-align: right;">Page 137</p> <p>1 program.</p> <p>2 Doesn't Mallinckrodt's current iteration</p> <p>3 of the SOM program try and understand where</p> <p>4 Mallinckrodt pills are going after the transaction</p> <p>5 occurs between Mallinckrodt and the distributor?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. After the transaction between Mallinckrodt</p> <p>8 and its customer? I just want to make sure I</p> <p>9 understood your question correctly.</p> <p>10 BY MR. KO:</p> <p>11 Q. The question is doesn't Mallinckrodt's</p> <p>12 current iteration of its SOM program try and understand</p> <p>13 where Mallinckrodt pills are going after the</p> <p>14 transaction between Mallinckrodt and the distributor?</p> <p>15 A. Yes.</p> <p>16 MR. O'CONNOR: Same objection.</p> <p>17 BY MR. KO:</p> <p>18 Q. And so in other words, Mallinckrodt's</p> <p>19 current iteration of its SOM program tries to</p> <p>20 understand knowledge of Mallinckrodt's customer's</p> <p>21 customer; is that accurate?</p> <p>22 MR. O'CONNOR: Objection to form.</p> <p>23 A. Yes, we're going above and beyond what the</p> <p>24 regulation calls for here in trying to accomplish that.</p>

<p style="text-align: right;">Page 138</p> <p>1 BY MR. KO:</p> <p>2 Q. And turning back to the purpose statement</p> <p>3 of this particular draft that's dated June of 2008.</p> <p>4 Is it your testimony that you don't</p> <p>5 believe this draft policy reflects an understanding of</p> <p>6 Mallinckrodt to try and know its customer's customer?</p> <p>7 MR. O'CONNOR: Objection --</p> <p>8 A. No, there was no regulation at that time.</p> <p>9 BY MR. KO:</p> <p>10 Q. I understand that there was no regulation.</p> <p>11 I'm just talking specifically about this document.</p> <p>12 A. Okay. So my interpretation of this</p> <p>13 document is between Mallinckrodt and its customer --</p> <p>14 the wholesaler distributor.</p> <p>15 Q. Understood. And are you aware of any --</p> <p>16 earlier we had discussed that document that had a</p> <p>17 chronology that Ms. Harper summarized for you.</p> <p>18 Do you recall that document?</p> <p>19 MR. O'CONNOR: Objection to form.</p> <p>20 A. Are you talking about the one that ends in</p> <p>21 6623? I'm sorry. Is that --</p> <p>22 BY MR. KO:</p> <p>23 Q. Yes.</p> <p>24 A. Okay. I just want to make sure we're on</p>	<p style="text-align: right;">Page 140</p> <p>1 A. So in our anti-diversion efforts, this is</p> <p>2 one of those times that we were going above and beyond</p> <p>3 what was called for in the regulations.</p> <p>4 BY MR. KO:</p> <p>5 Q. Well, that's not the question I asked.</p> <p>6 A. I'm sorry.</p> <p>7 Q. Is it your test --</p> <p>8 A. I misunderstood your question.</p> <p>9 Q. Sure. Is it your testimony today that you</p> <p>10 believe that it would be appropriate to not follow the</p> <p>11 advice of the DEA to know your customer's customer as</p> <p>12 of July 2010?</p> <p>13 MR. O'CONNOR: Objection to form.</p> <p>14 A. I'm telling you there's no regulation that</p> <p>15 requires us to do this, but we do do it.</p> <p>16 BY MR. KO:</p> <p>17 Q. I understand what your testimony is with</p> <p>18 respect to whether or not there is a regulation, but my</p> <p>19 question is simply whether or not you believe it would</p> <p>20 be appropriate for Mallinckrodt to not follow the</p> <p>21 advice of the DEA regarding its advice that you should</p> <p>22 know your customer's customer.</p> <p>23 MR. O'CONNOR: I'm going to object to form</p> <p>24 and asked and answered. This is the third time.</p>
<p style="text-align: right;">Page 139</p> <p>1 the same page.</p> <p>2 Q. Sure.</p> <p>3 A. Okay.</p> <p>4 Q. So we had discussed that you had agreed</p> <p>5 that Mallinckrodt knew at least as of July 2010 that it</p> <p>6 had an obligation to know its customer's customer?</p> <p>7 MR. O'CONNOR: Objection to form.</p> <p>8 A. So we didn't have an obligation to know</p> <p>9 our customer's customer, but we were being informed by</p> <p>10 the DEA in St. Louis that that's something we should be</p> <p>11 looking at.</p> <p>12 BY MR. KO:</p> <p>13 Q. So as of -- we had discussed how as of</p> <p>14 July 2010 you had been advised by the DEA that you</p> <p>15 should know your customer's customer; correct?</p> <p>16 A. Yes, but there's still no regulation.</p> <p>17 Q. I understand --</p> <p>18 A. Okay.</p> <p>19 Q. -- that your testimony is that there's no</p> <p>20 regulation or you believe that there's no obligation,</p> <p>21 but would it be appropriate, Mr. Gillies, if</p> <p>22 Mallinckrodt did not follow the advice of DEA at the</p> <p>23 time?</p> <p>24 MR. O'CONNOR: Objection to form.</p>	<p style="text-align: right;">Page 141</p> <p>1 A. So I have a legal --</p> <p>2 BY MR. KO:</p> <p>3 Q. You can answer.</p> <p>4 A. I have a legal question.</p> <p>5 Q. Why don't you answer -- try and answer the</p> <p>6 question first.</p> <p>7 MR. O'CONNOR: If you believe questions</p> <p>8 that concerns privilege, then we can go off the record</p> <p>9 and talk about it.</p> <p>10 BY MR. KO:</p> <p>11 Q. Let --</p> <p>12 A. Yes, I actually -- I do believe there's a</p> <p>13 legal issue that is problematic.</p> <p>14 MR. O'CONNOR: Okay.</p> <p>15 A. I just want to get a clarification.</p> <p>16 MR. O'CONNOR: Then I'd ask that we either</p> <p>17 move off the question or we can take a break.</p> <p>18 A. It should be really quick.</p> <p>19 BY MR. KO:</p> <p>20 Q. Yeah, let's not take a break.</p> <p>21 A. Okay.</p> <p>22 Q. You can discuss it with your counsel over</p> <p>23 the lunch break. We can go back on it.</p> <p>24 A. Okay.</p>

<p style="text-align: right;">Page 142</p> <p>1 Q. Do you recall seeing any documents or 2 reviewing any documents that suggest that the DEA had 3 advised Mallinckrodt of knowing their customer's 4 customer in the 2008 time period? 5 A. No. 6 Q. Do you recall seeing any documents other 7 than the document that's in front of you which 8 indicates Ms. Harper's comments to you regarding DEA 9 advice regarding knowledge of customer's customer -- 10 strike that. Let me ask again. 11 Prior to 2010, have you seen any documents 12 that reference an obligation or advice by the DEA 13 regarding Mallinckrodt knowing their customer's 14 customer? 15 A. Prior to this time frame? 16 Q. (Nodding "yes.") 17 A. No. 18 Q. And then going back to the Draft 3 that we 19 were discussing a moment ago. 20 A. Okay. 21 Q. Now, I know that we had discussed -- first 22 of all, you agree with me that this is a draft; 23 correct? 24 A. It says Draft 3.</p>	<p style="text-align: right;">Page 144</p> <p>1 do you recall seeing anything prior to June of 2008 2 that reflects a written memorialization of the 3 algorithm utilized by Mallinckrodt? 4 MR. O'CONNOR: Objection to form. 5 A. I can't recall that. 6 BY MR. KO: 7 Q. You can set this one aside. 8 A. Okay. 9 Q. We'll move on to Gillies -- now back on 10 track. Gillies Exhibit 11. 11 [Exhibit Mallinckrodt-Gillies-011 12 marked for identification.] 13 Q. And for the record, this is titled DEA 14 compliance procedure controlled substance suspicious 15 order monitoring, Draft 4, ending in Bates 296382. 16 So Mr. Gillies, this particular document 17 reflects in the top right-hand corner that it is Draft 18 4, published July 8th, 2008; correct? 19 A. Correct. 20 Q. And so this appears to be the fourth 21 iteration of the documents that we've been going over; 22 correct? 23 A. Yes. 24 Q. And by the way, do you have any</p>
<p style="text-align: right;">Page 143</p> <p>1 Q. And if you look, for example, like on Page 2 4, which we'll turn to here, there are still question 3 marks and blanks with respect to what to include in 4 this particular draft; correct? 5 A. Yes, I see those now. 6 Q. And in that particular section at the top 7 of Page 4, I believe there is a reference to an 8 algorithm to try and define a particular peculiar 9 order. 10 Do you see that portion of draft policy? 11 A. Yes. 12 Q. So is it accurate to say that this 13 particular draft is the first time that Mallinckrodt 14 tries to incorporate reference to an algorithm into its 15 written draft SOM policy? 16 MR. O'CONNOR: Objection to form. 17 A. So I don't recall whether there was 18 anything written prior to this, but -- 19 BY MR. KO: 20 Q. So is it fair to say that -- 21 A. But we did have an algorithm. 22 Q. I understand that you testified at length 23 that you believe there was an algorithm, but in terms 24 of an actual algorithm being memorialized in writing,</p>	<p style="text-align: right;">Page 145</p> <p>1 understanding of -- well, the originator of this 2 document is Karen Harper. Do you see that? 3 A. Yes. 4 Q. And I'll represent to you that in the 5 previous three versions that we looked at she was also 6 the originator. 7 Do you have any understanding of who Ms. 8 Harper circulated these draft policies to? 9 A. I do not. 10 Q. Do you have any understanding of whether 11 or not these draft procedures were circulated to anyone 12 outside of the DEA compliance team? 13 A. I believe -- yes. 14 Q. And who outside of the DEA compliance team 15 were these draft procedures circulated to? 16 A. Bill Ratliff. 17 Q. And correct me if I'm wrong, but I believe 18 you told me that he was part of the DEA compliance 19 team, or was he not? 20 MR. O'CONNOR: Objection to form. 21 A. I did not say that. 22 BY MR. KO: 23 Q. He was just part of the SOM team? 24 A. That's correct.</p>

<p style="text-align: right;">Page 146</p> <p>1 Q. So Bill Ratliff was never part of the DEA 2 compliance team? 3 A. I didn't say that either. 4 Q. I see. 5 A. I'm not aware of that. 6 Q. Understood. 7 A. But he was security, and then you had DEA 8 compliance. 9 Q. Understood. Other than Mr. Ratliff, are 10 you aware of anyone else that these draft DEA 11 compliance procedures would have been circulated to? 12 A. I'm unaware of who else they went to. 13 Q. Now, in the scope section of this 14 particular draft, there's a reference to the fact that 15 this particular draft applies -- I'll just read it so 16 the record is clear. 17 Scope, applies internally to Covidien 18 customer service group, information services group, DEA 19 compliance, and security for monitoring of controlled 20 substance orders received electronically or manually, 21 bulk or finished dosage products, for all active 22 accounts, new or established, from order placement to 23 shipment. 24 Did I read that correctly?</p>	<p style="text-align: right;">Page 148</p> <p>1 the 222 forms to make sure that what the customer 2 address and the ship to address in our records and 3 stuff matched. That was one of the SOM steps for bulk. 4 BY MR. KO: 5 Q. Okay. So that -- to be clear, the address 6 verification form was a feature unique to the bulk SOM 7 program? Is that your testimony? 8 A. Yeah, for the 222s. Yes. Uh-huh. 9 Q. Through the 222 forms? 10 A. Correct. 11 Q. And at any time in Mallinckrodt's history, 12 are you aware of whether or not there was a separate 13 bulk SOM program? 14 MR. O'CONNOR: Objection to form and 15 scope. 16 A. Again, I'm unaware of a separate one, so 17 the SOM program that I'm aware of included both. 18 BY MR. KO: 19 Q. I see. So as far as your understanding, 20 Mallinckrodt's SOM program governed both its bulk 21 product and its dosage products; correct? 22 A. Correct. 23 Q. And at least for purposes of this draft 24 procedure, it seems to make clear that the SOM program</p>
<p style="text-align: right;">Page 147</p> <p>1 A. Yes. 2 Q. So focusing on the portion that indicates 3 bulk or finished dosage products, what is the 4 difference -- can you explain to the court what the 5 difference is between the two? 6 A. Bulk -- the bulk products are at our St. 7 Louis facility. These are the manufacturing, and the 8 finished dosage products is at our Hobart facility for 9 the actual manufacturing of the tablets. 10 Q. So in other words, is it fair to say that 11 Hobart is where Mallinckrodt converts the actual 12 product into a pill, for example? Is that correct? 13 A. Correct. 14 Q. And the St. Louis facility is where 15 Mallinckrodt processes and manufactures the raw 16 product; correct? 17 A. Correct. 18 Q. And so do you have any understanding 19 whether or not Mallinckrodt ever had a separate SOM 20 program with respect to its bulk product relative to 21 its dosage products? 22 MR. O'CONNOR: Objection to form. 23 A. I don't believe it was separate, but as it 24 applied to bulk, there were address verifications from</p>	<p style="text-align: right;">Page 149</p> <p>1 is both for bulk and finished dosage products; correct? 2 A. Correct. 3 Q. For Mallinckrodt's current SOM program, is 4 there any sort of distinction or delineation made 5 between Mallinckrodt bulk and dosage products with 6 respect to SOM? 7 MR. O'CONNOR: Objection to form. 8 A. No. 9 BY MR. KO: 10 Q. Now, turning to the next page, Page 2 of 11 this particular policy, again we see definitions of 12 both peculiar and suspicious orders. Do you see that? 13 A. Yes. 14 Q. So is it accurate to say that this 15 particular draft has a definition of a peculiar order 16 that's consistent with the others, and it does not 17 specifically identify the peculiar order algorithm; is 18 that correct? 19 MR. O'CONNOR: Objection to form. 20 A. Yes. 21 BY MR. KO: 22 Q. And so is it accurate to state that as of 23 July 8th, 2008, Mallinckrodt had not incorporated an 24 algorithm into its SOM policy? Is that accurate?</p>

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<p>1 MR. O'CONNOR: Objection to form.</p> <p>2 A. No.</p> <p>3 BY MR. KO:</p> <p>4 Q. For purposes of the written policies that</p> <p>5 Mallinckrodt was attempting to create, is it accurate</p> <p>6 to say that there is no definition of -- or there's no</p> <p>7 indication in this document of a specific algorithm</p> <p>8 that's utilized for purposes of identifying a peculiar</p> <p>9 order?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. Sorry. I'm going to have to read this</p> <p>12 document to see whether that's an accurate statement or</p> <p>13 not.</p> <p>14 BY MR. KO:</p> <p>15 Q. Sure.</p> <p>16 A. So --</p> <p>17 MR. KO: And while you go over that</p> <p>18 document, maybe we can -- we can shoot for like a 12:45</p> <p>19 break for lunch. Is that good?</p> <p>20 MR. O'CONNOR: Sounds good.</p> <p>21 MR. KO: Okay.</p> <p>22 A. So there's no mention of algorithm in this</p> <p>23 document.</p> <p>24 BY MR. KO:</p>	<p>1 Q. So you don't have an understanding of</p> <p>2 what -- your testimony is that you don't have an</p> <p>3 understanding of what that algorithm consisted of, but</p> <p>4 you believe that there was an algorithm that was</p> <p>5 utilized at the time?</p> <p>6 A. That's correct.</p> <p>7 Q. And separate and apart from whether or not</p> <p>8 there was an algorithm utilized, for purposes of this</p> <p>9 particular document, the algorithm is not spelled out</p> <p>10 in this particular draft policy; correct?</p> <p>11 A. Correct.</p> <p>12 Q. You can set that one aside.</p> <p>13 A. Okay.</p> <p>14 Q. And I'll hand you a copy of what's going</p> <p>15 to be marked as Gillies Exhibit 12.</p> <p>16 [Exhibit Mallinckrodt-Gillies-012</p> <p>17 marked for identification.]</p> <p>18 Q. And for the record, Gillies Exhibit 12</p> <p>19 is -- ends in Bates 4154292.</p> <p>20 And Mr. Gillies, this is -- this</p> <p>21 particular draft procedure is dated November 4th, 2009;</p> <p>22 correct?</p> <p>23 A. Correct.</p> <p>24 Q. And unlike -- well, first of all, have you</p>
Page 151	Page 153
<p>1 Q. So as of July 8th, 2008, is it accurate to</p> <p>2 state that Mallinckrodt had not yet incorporated an</p> <p>3 algorithm into its suspicious order monitoring draft</p> <p>4 policy?</p> <p>5 MR. O'CONNOR: Objection to form.</p> <p>6 A. It's not listed in this policy.</p> <p>7 BY MR. KO:</p> <p>8 Q. So is it -- and my question was different.</p> <p>9 A. Okay.</p> <p>10 Q. As of July -- yes or no -- as of July 8th,</p> <p>11 2008, is it accurate to state that Mallinckrodt had not</p> <p>12 yet incorporated an algorithm into its suspicious order</p> <p>13 monitoring draft policy?</p> <p>14 MR. O'CONNOR: Same objection.</p> <p>15 A. So again, as I stated earlier, the word</p> <p>16 algorithm is not in here, but when it refers to</p> <p>17 established criteria, then I believe that to be the</p> <p>18 algorithm even though the word algorithm is not in this</p> <p>19 document.</p> <p>20 BY MR. KO:</p> <p>21 Q. And what was your understanding of what</p> <p>22 the established criteria was as of July 8th, 2008?</p> <p>23 A. I don't recall the algorithm, but there is</p> <p>24 a reference down here to [REDACTED]. I don't recall.</p>	<p>1 reviewed a procedure like this before?</p> <p>2 A. Yes.</p> <p>3 Q. And this particular procedure, unlike the</p> <p>4 ones that we were going over a moment ago with respect</p> <p>5 to SOM algorithms or criteria in particular, this one</p> <p>6 governs the new and existing customer account setups</p> <p>7 and ongoing reviews; is that accurate to say?</p> <p>8 A. That's what this subject is, yes.</p> <p>9 Q. And if we go on, the purpose of this</p> <p>10 document -- one of the purposes of this document is to</p> <p>11 establish a procedure outlining the process for</p> <p>12 monitoring new controlled substance customer accounts</p> <p>13 and ongoing review of existing controlled substance</p> <p>14 customer accounts.</p> <p>15 You see that?</p> <p>16 A. Yes.</p> <p>17 MR. O'CONNOR: Objection.</p> <p>18 BY MR. KO:</p> <p>19 Q. So did Mallinckrodt have -- prior to</p> <p>20 November of 2009, are you aware of any written policies</p> <p>21 or procedures governing the process for monitoring new</p> <p>22 and existing customer accounts of Mallinckrodt?</p> <p>23 A. I can't recall.</p> <p>24 MR. O'CONNOR: Objection to form and</p>

<p style="text-align: right;">Page 154</p> <p>1 scope.</p> <p>2 BY MR. KO:</p> <p>3 Q. Does the current iteration of</p> <p>4 Mallinckrodt's SOM program have any written policy or</p> <p>5 procedure related to new and existing customer</p> <p>6 accounts?</p> <p>7 MR. O'CONNOR: Same objections.</p> <p>8 A. I can't recall.</p> <p>9 BY MR. KO:</p> <p>10 Q. Are you aware, in addition to -- so</p> <p>11 obviously this is -- well, if you look at Page 3 of</p> <p>12 this document, there are some question marks --</p> <p>13 A. Sure.</p> <p>14 Q. -- with respect to what the policy should</p> <p>15 say. So this reflects that this is a draft; correct?</p> <p>16 A. I don't see draft on this document, so I'd</p> <p>17 be speculating.</p> <p>18 Q. Would you agree with me that a document</p> <p>19 that includes some question marks would not be a final</p> <p>20 or formal policy?</p> <p>21 MR. O'CONNOR: Objection to form.</p> <p>22 A. I don't believe it would be.</p> <p>23 BY MR. KO:</p> <p>24 Q. And I know I asked you about prior to this</p>	<p style="text-align: right;">Page 156</p> <p>1 and procedures in place with respect to its duties</p> <p>2 under the Controlled Substances Act?</p> <p>3 A. Yes.</p> <p>4 Q. And one of those policies and procedures</p> <p>5 is reflected by this draft policy; correct?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. Again, I'd have to read this entire</p> <p>8 document, but --</p> <p>9 BY MR. KO:</p> <p>10 Q. Well, let's take a step back to the</p> <p>11 question I asked before.</p> <p>12 A. Okay.</p> <p>13 Q. You had indicated that there were certain</p> <p>14 policies and procedures in place with respect to</p> <p>15 Mallinckrodt's duties under the CSA; correct?</p> <p>16 A. Yes.</p> <p>17 Q. And what did those policies and procedures</p> <p>18 consist of other than those governing its SOM</p> <p>19 obligations?</p> <p>20 A. Security.</p> <p>21 Q. Anything else?</p> <p>22 A. Not that I can recall.</p> <p>23 Q. Do you know whether or not Mallinckrodt</p> <p>24 had any policies and procedures with respect to its</p>
<p style="text-align: right;">Page 155</p> <p>1 time period, but following November of 2009, do you</p> <p>2 recall seeing any written policies or procedures</p> <p>3 governing existing customer accounts or new customer</p> <p>4 accounts?</p> <p>5 A. Yes.</p> <p>6 Q. And when -- approximately when were those</p> <p>7 policies in place?</p> <p>8 A. I don't recall the dates.</p> <p>9 Q. At some point after 2009, though; correct?</p> <p>10 A. That's my recollection.</p> <p>11 Q. And approximately how many policies have</p> <p>12 you either reviewed or has Mallinckrodt implemented</p> <p>13 since 2009?</p> <p>14 MR. O'CONNOR: Objection to form and</p> <p>15 scope.</p> <p>16 A. My recollection is that there's several</p> <p>17 that I reviewed.</p> <p>18 BY MR. KO:</p> <p>19 Q. So in addition to -- well, Mallinckrodt</p> <p>20 had certain policies and procedures with respect to its</p> <p>21 SOM program, as we discussed; correct?</p> <p>22 A. Correct.</p> <p>23 Q. And in addition to those policies and</p> <p>24 procedures, did Mallinckrodt also have other policies</p>	<p style="text-align: right;">Page 157</p> <p>1 customer audit programs?</p> <p>2 MR. O'CONNOR: Objection to form.</p> <p>3 A. Yes, I think we did.</p> <p>4 BY MR. KO:</p> <p>5 Q. And was there ever a time when</p> <p>6 Mallinckrodt had a policy or procedure with respect to</p> <p>7 specific customer accounts that it had deemed to be</p> <p>8 potentially suspicious?</p> <p>9 MR. O'CONNOR: Objection to form.</p> <p>10 A. I don't recall that.</p> <p>11 BY MR. KO:</p> <p>12 Q. Okay. Fair enough. You can set this one</p> <p>13 aside, and I want to -- before breaking for lunch,</p> <p>14 let's just go over one more document.</p> <p>15 A. Okay.</p> <p>16 Q. This will be Gillies Exhibit 13.</p> <p>17 [Exhibit Mallinckrodt-Gillies-013</p> <p>18 marked for identification.]</p> <p>19 Q. For the record, this ends in Bates</p> <p>20 4154297. And this particular document is dated</p> <p>21 November 4th, 2009.</p> <p>22 Do you see that, Mr. Gillies?</p> <p>23 A. Yes.</p> <p>24 Q. And this -- the subject of this particular</p>

<p style="text-align: right;">Page 158</p> <p>1 policy is identification and review of peculiar orders, 2 controlled substance suspicious order monitoring 3 program. 4 Did I read that correctly? 5 A. Yes. 6 Q. And Karen Harper continues to be the 7 originator of this document? 8 A. Yes. 9 Q. And turning your attention to the second 10 page of this document, there's a reference to the [REDACTED] 11 algorithm or criteria that we were discussing 12 previously; correct? 13 A. Yes. 14 Q. And the specific definition of a peculiar 15 order as defined by this policy is an order that is [REDACTED] 16 [REDACTED] the average amount of product ordered during the 17 previous 18 months by DEA reporting class; correct? 18 A. Yes. 19 Q. So is it accurate to say that as of 20 November 2009 -- or strike that. 21 Is it accurate to say that November 2009 22 is the first time there is mention of a specific 23 algorithm that will be utilized to determine whether or 24 not an order is peculiar in an SOM written policy?</p>	<p style="text-align: right;">Page 160</p> <p>1 A. Correct. 2 BY MR. KO: 3 Q. And this particular algorithm or formula 4 that is being utilized -- does this refresh your 5 recollection at all as to how long prior to November 6 2009 Mallinckrodt may have been utilizing this formula? 7 MR. O'CONNOR: Objection to form. 8 A. No. 9 MR. KO: Okay. We can take a break for 10 lunch. 11 MR. O'CONNOR: Sounds good. 12 A. May I take this document so I can ask that 13 legal question? 14 MR. KO: You can -- let's -- 15 MR. O'CONNOR: We can go off the record. 16 MR. KO: Yeah, we can go off the record. 17 THE VIDEOGRAPHER: We are going off the 18 record at 12:47 PM. 19 [A recess was taken.] 20 THE VIDEOGRAPHER: We are back on the 21 record at 1:37 PM. 22 BY MR. KO: 23 Q. Welcome back from lunch, Mr. Gillies. 24 A. Thank you.</p>
<p style="text-align: right;">Page 159</p> <p>1 MR. O'CONNOR: Objection to form. 2 A. No. 3 BY MR. KO: 4 Q. Did you recall seeing any other documents 5 prior that predate November of 2009 that memorialize 6 the written -- or that memorialize the algorithm that 7 Mallinckrodt was going to utilize for purposes of 8 defining a peculiar order? 9 A. Yes, I believe there was a document that 10 you showed me earlier. Wasn't there a reference to the 11 algorithm in that? 12 Q. For purposes of -- I see what you're 13 saying, but for purposes -- I'm just asking for 14 purposes of defining a peculiar order in the draft 15 written policy, is this the first time you see a 16 reference made to an algorithm? 17 A. Okay. In that particular definition? 18 Q. Correct. 19 A. Yes. 20 Q. And in the prior drafts that we had seen, 21 there was no mention to the specific algorithm that was 22 being utilized for purposes of defining a peculiar 23 order; correct? 24 MR. O'CONNOR: Objection to form.</p>	<p style="text-align: right;">Page 161</p> <p>1 Q. Before we broke, we were discussing 2 Exhibit 13, and I just had a couple follow-up questions 3 before we move on to the next exhibit. 4 Can you turn to the top of Page 3? And at 5 the top of Page 3 there's a reference to -- there's a 6 Number 4, and there's a reference to reviewing the 7 order based on the criteria. Do you see that? 8 A. Number 4, yes. 9 Q. And then there's some language that says, 10 quote, we should probably rephrase this to something 11 like place the order in appropriate hold status while 12 being evaluated, end quote. 13 Did I read that correctly? 14 A. Yes. 15 Q. And so does that -- does this language 16 indicate that this version is still in draft form? 17 A. I don't know that, but I think it's fair 18 to say that. 19 Q. So this particular document dated 20 11-4-2009 regarding Mallinckrodt's controlled substance 21 suspicious order monitoring program appears to be a 22 draft; is that fair to say? 23 A. Yes. 24 Q. You can set that one aside. And I'm going</p>

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1 to now hand you a copy of what will be marked as
2 Gillies Exhibit --
3 [Exhibit Mallinckrodt-Gillies-014
4 marked for identification.]
5 Q. This is one document, which for the record
6 is a cover e-mail and an attachment, and the cover
7 e-mail is Bates MNK-T1_0000264240.
8 And then the attachment ends in 264260,
9 and I'll represent for the record and for counsel there
10 are a series of attachments to this cover e-mail, and
11 this, for efficiency purposes, is just one of the
12 attachments that's referenced in the e-mail.
13 A. Okay.
14 Q. First let's turn to the policy -- the
15 draft policy ending in 260.
16 This particular policy is dated October
17 29th, 2010; correct?
18 A. Yes.
19 Q. And again, this is a policy that governs
20 Mallinckrodt's SOM program; is that accurate?
21 A. Yes.
22 Q. And in the prior version that we were --
23 if you go to the -- if you turn to Page 2 of this
24 policy.

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1 A. What -- I'm sorry. Which one? The
2 current one you just gave me?
3 Q. Yeah, the one I just gave you.
4 A. Oh, okay. Okay.
5 Q. Sorry. I was just giving your counsel an
6 extra copy.
7 A. Oh, okay.
8 Q. Page 2 of this policy has a reference to
9 peculiar order like the other ones; correct?
10 A. Yes.
11 Q. And here you have a definition of a
12 peculiar order as being one that is, quote, controlled
13 substance order that meets an internal established
14 criteria of [REDACTED] the average amount of product ordered
15 during the previous 12 months by DEA reporting class.
16 Did I read that correctly?
17 A. Yes.
18 Q. And so in the prior version we just looked
19 at, the peculiar order algorithm was [REDACTED] the average
20 amount of product ordered during the prior 18 months by
21 DEA reporting class; correct?
22 A. Correct.
23 Q. So does this policy reflect a revision in
24 the peculiar order algorithm to [REDACTED] the prior 12-month

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1 order history?
2 A. Yes.
3 MR. O'CONNOR: Objection.
4 BY MR. KO:
5 Q. And do you have any understanding of why
6 this change occurred with respect to Mallinckrodt's
7 peculiar order algorithm?
8 A. It's my understanding under the [REDACTED] that
9 there were too many hits on the algorithm, and our
10 outside DEA consultant advised that if you have too
11 many hits hitting your peculiar order report and none
12 of them are, you should change it to focus a little bit
13 more on those that could truly be peculiar.
14 BY MR. KO:
15 Q. And this outside DEA consultant, was that
16 Mr. Sapienza?
17 A. Sapienza. Yeah.
18 Q. Sapienza? Okay. And other than Mr.
19 Sapienza, did Mallinckrodt obtain any other advice with
20 respect to changing the algorithm from [REDACTED] to [REDACTED]?
21 A. Not that I'm --
22 MR. O'CONNOR: Object -- I'm just going to
23 object to the extent that involves any attorney-client
24 communications.

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1 A. Not that I'm aware of, other than their
2 experience with the previous algorithm and then the
3 information they got from the consultant.
4 BY MR. KO:
5 Q. And so in addition to changing the formula
6 from [REDACTED] to [REDACTED] the average amount, the time period
7 that's reviewed is decreased from 18 months to 12
8 months as well; correct?
9 A. Yes.
10 Q. And so again, just so the record is clear,
11 your testimony is that the intent behind doing this was
12 to minimize the amount of peculiar order reports that
13 were being produced?
14 MR. O'CONNOR: Objection to form.
15 A. From the experience of reviewing the
16 previous algorithm reports, it was -- there were too
17 many hits on the system, and an outside consultant said
18 if there's too many, then it's -- and none of them were
19 turning out to be suspicious, that we needed to tighten
20 that up a little bit.
21 BY MR. KO:
22 Q. And the reason why you moved down from 18
23 months to 12 months and up from [REDACTED] to [REDACTED] is to, as you
24 say, tighten up the amount of orders that were reported

<p style="text-align: right;">Page 166</p> <p>1 under the peculiar order standard?</p> <p>2 A. That were hitting the report; correct.</p> <p>3 Q. Now, turning to the cover e-mail that</p> <p>4 attaches this particular document, there's an e-mail</p> <p>5 from Karen Harper to Howard Davis dated November 18th,</p> <p>6 2010. Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Do you know who Howard Davis is?</p> <p>9 A. He was another outside consultant that we</p> <p>10 hired on a contract basis.</p> <p>11 Q. And was he another outside consultant that</p> <p>12 Mallinckrodt hired on a contract basis to specifically</p> <p>13 advise Mallinckrodt regarding its suspicious order</p> <p>14 monitoring program?</p> <p>15 MR. O'CONNOR: Objection to form.</p> <p>16 A. I believe that to be the main reason.</p> <p>17 BY MR. KO:</p> <p>18 Q. Do you have any understanding of what</p> <p>19 other reasons he may have been retained for?</p> <p>20 A. I can't recall the details in the contract</p> <p>21 specifically whether there were other items that he</p> <p>22 would assist on.</p> <p>23 Q. And separate and apart from the contract,</p> <p>24 do you have any understanding of what services Howard</p>	<p style="text-align: right;">Page 168</p> <p>1 regarding its SOM program; correct?</p> <p>2 A. That's what I said, yes.</p> <p>3 Q. At the beginning of this e-mail, Ms.</p> <p>4 Harper states Howard, please revise the QSP order</p> <p>5 monitoring document incorporating recent program</p> <p>6 enhancements with recent activities.</p> <p>7 Do you see that portion of the e-mail?</p> <p>8 A. I do.</p> <p>9 Q. And do you have an understanding of what</p> <p>10 QSP order monitoring document is referring to?</p> <p>11 A. No.</p> <p>12 Q. Do you have any reason to believe that Ms.</p> <p>13 Harper is not asking Mr. Davis to revise the SOM policy</p> <p>14 that we were just looking at that's included as an</p> <p>15 attachment to this exhibit?</p> <p>16 MR. O'CONNOR: Objection to form.</p> <p>17 A. Again, I'm unfamiliar with what she's</p> <p>18 referring to as the QSP order monitoring document and</p> <p>19 this attached document. I don't see a reference to</p> <p>20 that QSP, so I don't know.</p> <p>21 BY MR. KO:</p> <p>22 Q. Fair enough.</p> <p>23 A. Okay.</p> <p>24 Q. Do you have -- sure. Do you have any</p>
<p style="text-align: right;">Page 167</p> <p>1 Davis provided when he was retained as an outside</p> <p>2 consultant outside of advice he gave on Mallinckrodt's</p> <p>3 SOM program?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. Not sure I'm understanding the question.</p> <p>6 Work outside of work he was doing for Mallinckrodt?</p> <p>7 BY MR. KO:</p> <p>8 Q. No, I'm only talking about with respect to</p> <p>9 work he did for Mallinckrodt.</p> <p>10 A. Okay.</p> <p>11 Q. So let me rephrase. Because in response</p> <p>12 to my question a moment ago, you were referencing the</p> <p>13 contract.</p> <p>14 A. Uh-huh.</p> <p>15 Q. And I don't mean to put you through a</p> <p>16 memory test of what the contract may or may not have</p> <p>17 said. I'm just simply asking you do you recall whether</p> <p>18 or not Mallinckrodt utilized Mr. Davis for any other</p> <p>19 purpose outside of advising Mallinckrodt regarding its</p> <p>20 suspicious order monitoring program?</p> <p>21 A. Not that I can recall.</p> <p>22 Q. So it's fair to say that the primary</p> <p>23 reason why Mallinckrodt retained Mr. Davis was to</p> <p>24 advise -- was for Mr. Davis to advise Mallinckrodt</p>	<p style="text-align: right;">Page 169</p> <p>1 understanding of whether or not Mr. Davis was ever</p> <p>2 specifically asked to revise a Mallinckrodt suspicious</p> <p>3 order monitoring policy?</p> <p>4 A. No.</p> <p>5 Q. Let me quickly hand you a copy of what's</p> <p>6 going to be marked as Gillies Exhibit 15.</p> <p>7 [Exhibit Mallinckrodt-Gillies-015</p> <p>8 marked for identification.]</p> <p>9 Q. And I apologize. I do believe this</p> <p>10 exhibit has been referenced in other documents, but for</p> <p>11 purposes of today we'll just go ahead and call it</p> <p>12 Gillies Exhibit 15. And it reflects a November 2nd,</p> <p>13 2010, memorandum from Howard Davis to Karen Harper</p> <p>14 ending in Bates 269399.</p> <p>15 Mr. Gillies, does this document look</p> <p>16 familiar to you?</p> <p>17 A. Yes.</p> <p>18 Q. Is this a document that you reviewed in</p> <p>19 preparation for this deposition today?</p> <p>20 MR. O'CONNOR: You can answer generally</p> <p>21 whether you've reviewed it.</p> <p>22 A. Yes.</p> <p>23 BY MR. KO:</p> <p>24 Q. And in this document, Mr. Davis makes</p>

<p style="text-align: right;">Page 170</p> <p>1 reference to a certain document titled Mallinckrodt</p> <p>2 standard operating procedure SOPC hyphen six --</p> <p>3 A. Yes.</p> <p>4 Q. -- comp 3.0. Do you see that?</p> <p>5 A. I'm sorry. That's C hyphen -- where are</p> <p>6 you at that you're referencing? Because you said a</p> <p>7 six, and I don't see a six, and I just want to make</p> <p>8 sure. Is the six the S that's there?</p> <p>9 Q. Sure. I may have misspoke.</p> <p>10 A. Okay. I'm sorry.</p> <p>11 Q. Let me be clear.</p> <p>12 A. Okay.</p> <p>13 Q. So the record is clear, Mr. Davis states,</p> <p>14 quote, reference is made to Mallinckrodt standard</p> <p>15 operating procedure SOPC-S comp 3.0 --</p> <p>16 A. Okay. Thank you.</p> <p>17 Q. -- entitled identification and review of</p> <p>18 peculiar orders.</p> <p>19 A. Okay.</p> <p>20 Q. Did I read that correctly?</p> <p>21 A. Yes.</p> <p>22 Q. Is it fair to say that Mr. Davis is</p> <p>23 referencing the standard operating procedure referenced</p> <p>24 as part of Exhibit 14 that we just looked at a moment</p>	<p style="text-align: right;">Page 172</p> <p>1 long he was actually retained?</p> <p>2 MR. O'CONNOR: Objection to form.</p> <p>3 A. My belief was less than a year.</p> <p>4 BY MR. KO:</p> <p>5 Q. Less than a year?</p> <p>6 By the way, do you know who Mr. Davis is?</p> <p>7 A. I know who he is now.</p> <p>8 Q. You didn't know him -- did you know him --</p> <p>9 at the time you joined Mallinckrodt in 2012, did you</p> <p>10 know of Howard Davis?</p> <p>11 A. I did not.</p> <p>12 Q. I'm going to hand you a copy of what's</p> <p>13 going to be marked as or has been marked as Gillies</p> <p>14 Exhibit 16.</p> <p>15 [Exhibit Mallinckrodt-Gillies-016</p> <p>16 marked for identification.]</p> <p>17 Q. And I just have a few questions about</p> <p>18 this.</p> <p>19 For the record, this is a document ending</p> <p>20 in Bates 264275, and it is the global controlled</p> <p>21 substance compliance procedure as of January 4th, 2011.</p> <p>22 And you see, Mr. Gillies, that this is --</p> <p>23 continues to be another version of the -- of</p> <p>24 Mallinckrodt's SOM policy; is that fair to say?</p>
<p style="text-align: right;">Page 171</p> <p>1 ago?</p> <p>2 A. Yes.</p> <p>3 Q. And you understood both in your review of</p> <p>4 this memorandum and in your preparations that Mr. Davis</p> <p>5 did indeed review certain SOM procedures and policies</p> <p>6 of Mallinckrodt; correct?</p> <p>7 A. Correct.</p> <p>8 Q. And this memorandum reflects his review</p> <p>9 and advice to Karen Harper regarding this particular</p> <p>10 SOM policy; correct?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. Yes.</p> <p>13 BY MR. KO:</p> <p>14 Q. That's all the questions I have on that.</p> <p>15 Set that one aside.</p> <p>16 By the way, do you have any understanding</p> <p>17 of how long Mr. Davis was retained as an outside</p> <p>18 consultant for Mallinckrodt?</p> <p>19 A. A short time, was my recollection, and his</p> <p>20 contract was not renewed.</p> <p>21 Q. And do you -- I'm trying to get an</p> <p>22 understanding of what you mean by short time. Do you</p> <p>23 recall whether or not it was half a year? Are you</p> <p>24 talking a year? Do you have any understanding of how</p>	<p style="text-align: right;">Page 173</p> <p>1 A. Yes.</p> <p>2 Q. And it's dated January 4th, 2011?</p> <p>3 A. Yes.</p> <p>4 Q. And for this particular draft or version,</p> <p>5 the peculiar order definition remains the same as the</p> <p>6 previous version we looked at; correct?</p> <p>7 A. Correct.</p> <p>8 Q. So just so the record is clear, as of</p> <p>9 January of 2011, the peculiar order algorithm utilized</p> <p>10 by Mallinckrodt was a criteria reflecting [REDACTED]</p> <p>11 the average amount of the product ordered during the</p> <p>12 previous 12 months by DEA reporting class; correct?</p> <p>13 A. Yes.</p> <p>14 Q. You can set that one aside.</p> <p>15 I'm now going to hand you a copy of what</p> <p>16 will be marked as Gillies Exhibit 17, which for the</p> <p>17 record is a cover e-mail from April 7th, 2011, ending</p> <p>18 in Bates 264199.</p> <p>19 [Exhibit Mallinckrodt-Gillies-017</p> <p>20 marked for identification.]</p> <p>21 Q. And an attachment ending in 264199.</p> <p>22 MR. KO: Here you go. You can have it.</p> <p>23 MR. O'CONNOR: Thanks.</p> <p>24 A. Okay.</p>

<p style="text-align: right;">Page 174</p> <p>1 BY MR. KO:</p> <p>2 Q. Just a few questions on this as well.</p> <p>3 Turn to the attachment.</p> <p>4 A. Yeah, I'm sorry. What did you say the</p> <p>5 number on the attachment was?</p> <p>6 Q. The attachment ended in Bates 264200.</p> <p>7 A. Okay. Thanks.</p> <p>8 Q. I may have misspoke. Yeah, you're right.</p> <p>9 The cover e-mail ends in 199.</p> <p>10 A. Okay.</p> <p>11 Q. The attachment ends in 200.</p> <p>12 A. I just wanted to make sure we were looking</p> <p>13 at the same document.</p> <p>14 Q. Yeah. Thank you for that clarification.</p> <p>15 So this is another version or draft of</p> <p>16 Mallinckrodt's SOM written policy dated March 28th,</p> <p>17 2011; correct?</p> <p>18 A. Yes.</p> <p>19 Q. And by this, just so the record is clear,</p> <p>20 I'm referring to the document ending in Bates 200.</p> <p>21 And turning to the next page, again you</p> <p>22 see a definition of peculiar order; correct?</p> <p>23 A. Yes.</p> <p>24 Q. And the definition of a peculiar order</p>	<p style="text-align: right;">Page 176</p> <p>1 revisions to this particular document; correct?</p> <p>2 A. She's asking her to clean up the format.</p> <p>3 Q. Okay. Fair enough.</p> <p>4 A. Okay.</p> <p>5 Q. In the April -- in the corresponding April</p> <p>6 7th e-mail from Eileen to Karen --</p> <p>7 A. Okay.</p> <p>8 Q. -- Eileen appears to make some additions</p> <p>9 to the document; is that correct?</p> <p>10 A. I'm sorry. I didn't read that part.</p> <p>11 So -- yes.</p> <p>12 Q. So does this e-mail reflect that the</p> <p>13 attachment ending in Bates 200 is a draft written</p> <p>14 policy of Mallinckrodt's SOM program?</p> <p>15 A. Again, it doesn't say draft on here. So</p> <p>16 she could have been making some enhancements to an</p> <p>17 actual policy.</p> <p>18 Q. I understand that. But as it relates to</p> <p>19 this particular -- I have a specific question with</p> <p>20 respect to this policy --</p> <p>21 A. Okay.</p> <p>22 Q. -- that's attached to this particular</p> <p>23 e-mail.</p> <p>24 A. Right.</p>
<p style="text-align: right;">Page 175</p> <p>1 remains unchanged from the prior two versions; correct?</p> <p>2 A. Correct.</p> <p>3 Q. So as of March 28th, 2011, the formula</p> <p>4 utilized by Mallinckrodt to determine whether or not an</p> <p>5 order was peculiar was to determine whether or not the</p> <p>6 order was [REDACTED] the average amount of product</p> <p>7 ordered during the previous 12 months by DEA reporting</p> <p>8 class; correct?</p> <p>9 A. Correct.</p> <p>10 Q. And going back to the cover e-mail ending</p> <p>11 in 199, I believe there's a reference made to a --</p> <p>12 MR. KO: Thanks, Andrew.</p> <p>13 BY MR. KO:</p> <p>14 Q. Well, let me ask it this way. So there's</p> <p>15 a -- this is an e-mail exchange between Eileen</p> <p>16 Spaulding and Karen Harper from the March and April of</p> <p>17 2011 time period; correct?</p> <p>18 A. Yes.</p> <p>19 Q. And is it fair to say that Karen is asking</p> <p>20 Eileen to make some revisions to this particular</p> <p>21 policy? Correct?</p> <p>22 A. Could you repeat your question?</p> <p>23 Q. Sure. In the underlying e-mail dated</p> <p>24 March 30th, 2011, Karen is asking Eileen to make some</p>	<p style="text-align: right;">Page 177</p> <p>1 Q. This document that ends in Bates 200</p> <p>2 appears to be a draft SOM policy of Mallinckrodt;</p> <p>3 correct?</p> <p>4 A. I don't know that.</p> <p>5 Q. So I'll represent to you that this</p> <p>6 attachment that is referenced in Eileen's e-mail to</p> <p>7 Karen is in fact the attachment that's part of this</p> <p>8 e-mail.</p> <p>9 A. Okay.</p> <p>10 Q. And so with that representation, would you</p> <p>11 agree with me that the policy dated March 28th, 2011,</p> <p>12 ending in dash 200 is a draft version of Mallinckrodt's</p> <p>13 SOM policy, or is it your belief -- or you can't answer</p> <p>14 that question?</p> <p>15 A. Well, again, I'll stick with my original</p> <p>16 answer, which is no, it could be revisions to an</p> <p>17 existing policy. So I don't know that to be a draft.</p> <p>18 I guess that's what I'm saying.</p> <p>19 So if I knew this to be a draft, fine, but</p> <p>20 I don't know this to be a draft, so these could be</p> <p>21 revisions she made to an existing policy.</p> <p>22 Q. Fair enough.</p> <p>23 A. Okay.</p> <p>24 Q. Do you know -- have you seen -- in any of</p>

<p style="text-align: right;">Page 178</p> <p>1 the review of your documents in preparation for this 2 deposition, have you ever seen an SOM written policy in 3 this time period of March 28th, 2011, that reflects a 4 formal written policy of Mallinckrodt? 5 MR. O'CONNOR: Objection to form. 6 A. This may have been one of the documents 7 that I reviewed, and it appears to me to be a formal 8 written policy. 9 BY MR. KO: 10 Q. But in the cover e-mail, there are some 11 changes being made; is that fair? 12 A. That's fair. 13 Q. And so all I'm asking is that for this 14 particular document ending in dash 200, that appears to 15 be a draft policy because Eileen and Karen are making 16 some slight changes to it; is that correct? 17 A. No, that's not my testimony. My testimony 18 is that I don't know this to be a draft, and this could 19 be a formal policy in play that has some revisions made 20 to it. That's -- 21 Q. Sure. Fair enough. Do you recall seeing 22 a formal policy during the March 2011 time period 23 regarding Mallinckrodt's SOM program? 24 A. Again, I may have reviewed this policy.</p>	<p style="text-align: right;">Page 180</p> <p>1 A. Yes. 2 Q. And it indicates that she is senior 3 manager of controlled substance compliance; correct? 4 A. Yes. 5 Q. And earlier I know you had said that you 6 were unaware of whether or not there was controlled 7 substance compliance group. Does this refresh your 8 recollection at all that there was in fact such a group 9 at Mallinckrodt? 10 A. So I'm going to take this that the DEA 11 compliance and the controlled substance compliance are 12 the same. 13 Q. Okay. Fair enough. So is it your 14 understanding that there were certain times at 15 Mallinckrodt where the DEA compliance group was also 16 referred to as the controlled substance compliance 17 group? 18 A. So my recollection is I only knew that 19 group as DEA compliance. 20 Q. And you have no recollection of whether or 21 not there was an actual or formal group called the 22 controlled substance compliance group at Mallinckrodt? 23 MR. O'CONNOR: Objection to form. 24 A. I'm unaware of that, and from looking at</p>
<p style="text-align: right;">Page 179</p> <p>1 Q. And is it your testimony that Mallinckrodt 2 did in fact have a formal written policy as of 2011 3 regarding its SOM program? 4 MR. O'CONNOR: Objection to form. 5 A. That's my understanding. 6 BY MR. KO: 7 Q. And who informed you that the particular 8 version that you may have looked at was in fact the 9 formal policy regarding Mallinckrodt's SOM program? 10 A. I didn't say anybody did. I said that I 11 may have reviewed this during that period and made that 12 conclusion on my own. 13 Q. I see. We can set that one aside. 14 A. Okay. 15 Q. We will now go over what's been marked as 16 Gillies Exhibit 18. Excuse me. 17 [Exhibit Mallinckrodt-Gillies-018 18 marked for identification.] 19 Q. And for the record, this ends in Bates 20 259166, and this is titled Mallinckrodt suspicious 21 order monitoring procedure dated August 8th, 2011. 22 On this particular document, the 23 originator continues to be Karen Harper. Do you see 24 that?</p>	<p style="text-align: right;">Page 181</p> <p>1 this title I believe them to be the same. 2 BY MR. KO: 3 Q. And do you have any understanding -- or 4 did you review any documents that predate August 2011 5 that may have referenced a controlled substance 6 compliance group? 7 A. So some of the previous documents that you 8 showed me had that same title -- or that same name 9 after Karen's title, so the answer to your question is 10 yes. 11 Q. But -- and your testimony is that you 12 believe them to be essentially synonymous; is that 13 correct? 14 A. That's correct. 15 Q. And for this particular document, if you 16 look at the top of Page 2, the definition of peculiar 17 order is again set forth. Do you see that? 18 A. Yes. 19 Q. And as with the previous three versions 20 that we have looked at, the definition of a peculiar 21 order remains unchanged. Is that accurate? 22 A. Yes. 23 Q. So as of August 8th, 2011, so the record 24 is clear, Mallinckrodt utilized a peculiar order</p>

<p>Page 182</p> <p>1 algorithm which identified a peculiar order as one 2 being an order that was [REDACTED] the average amount 3 of product ordered by -- or ordered during the previous 4 12 months by DEA reporting class; correct? 5 A. Yes. 6 Q. Set that one aside. Move on to what's 7 going to be marked as Gillies Exhibit 19. And this 8 document ends in Bates 571916. 9 [Exhibit Mallinckrodt-Gillies-019 10 marked for identification.] 11 Q. So earlier today we had discussed the fact 12 that Mallinckrodt had a two-tier or sometimes 13 three-tier structure in identifying suspicious orders; 14 correct? 15 A. Correct. 16 Q. And in all of the documents that we just 17 looked at and all the policies, the definition of a 18 peculiar order -- or excuse me -- the tier system in 19 identifying a suspicious order included an initial 20 determination of whether or not an order was peculiar; 21 correct? 22 A. Correct. 23 Q. And at some point in time Mallinckrodt 24 moved to a definition -- or strike that.</p>	<p>Page 184</p> <p>1 suspicious orders. Is that fair to say? 2 A. Yes. 3 Q. And the change -- is it accurate to say 4 that this document reflects a description of how 5 Mallinckrodt is moving from a peculiar order 6 classification or system to an unusual order system? 7 MR. O'CONNOR: Objection to form. 8 A. Yes. 9 BY MR. KO: 10 Q. And in this document, there's an 11 indication that, quote, target date for go live for the 12 unusual order detection system is March 1st, 2012. 13 Did I read that correctly? 14 A. Yes. 15 Q. Do you have any reason to dispute that the 16 unusual order detection system was in fact implemented 17 at some point in early 2012? 18 A. I think that's accurate. 19 Q. And can you explain to the court what the 20 difference is between -- or can you explain to the 21 court why there was a change made to the unusual order 22 system? 23 MR. O'CONNOR: Objection to form. 24 A. No.</p>
<p>Page 183</p> <p>1 At some point in time Mallinckrodt removed 2 the definition of a peculiar order for purposes of 3 identifying a suspicious order; is that accurate? 4 MR. O'CONNOR: Objection to form. 5 A. I'm not aware of that. 6 BY MR. KO: 7 Q. You have no recollection of whether or not 8 Mallinckrodt had moved to a definition of an unusual 9 order for purposes of identifying a suspicious order? 10 A. I'm sorry. Yes. 11 Q. And that occurred in generally the late 12 2011, early 2012 time period; correct? 13 A. Yes. 14 Q. And this particular document -- it's not 15 in the same format as all those other policies, but 16 it's titled modifications to procedures for 17 identification and review of unusual orders. Correct? 18 A. Yes. 19 Q. And it appears to be dated December 8th, 20 2011? 21 A. Yes. 22 Q. And there's a description -- we don't need 23 to go over in detail, but there's a description of how 24 the then-existing algorithm worked for identifying</p>	<p>Page 185</p> <p>1 BY MR. KO: 2 Q. You don't have an understanding of why 3 Mallinckrodt changed from a peculiar order system to an 4 unusual system? 5 MR. O'CONNOR: Objection to form. 6 A. I believe them to be synonymous. 7 BY MR. KO: 8 Q. So was this just a matter of changing 9 terminology? 10 MR. O'CONNOR: Objection to form. 11 A. That's my understanding. 12 BY MR. KO: 13 Q. And here there's a reference made I 14 believe for the first time to the three-tier system 15 that you were alluding to earlier. Do you see 16 reference to that? 17 A. I do. 18 Q. And can you describe what those three 19 tiers were? 20 A. Tier 1 was the big three distributors plus 21 H.D. Smith, oxycodone 15s, and oxycodone 30s. 22 Tier 2 were the other distributors and all 23 their products plus the big three and H.D. Smith's 24 other products.</p>

<p style="text-align: right;">Page 186</p> <p>1 And then Tier 3 were new SKUs outside of</p> <p>2 those products, and that was used for a short time and</p> <p>3 then incorporated into the other two tiers.</p> <p>4 Q. Okay. And approximately how long was this</p> <p>5 three-tier system utilized?</p> <p>6 A. I believe approximately three to six</p> <p>7 months, maybe.</p> <p>8 Q. In the 2012 time period?</p> <p>9 A. Yes.</p> <p>10 Q. And turning back to this document, there</p> <p>11 actually is a reference made underneath the general</p> <p>12 section we were just looking at about the tiers. Do</p> <p>13 you see that -- Tier 1?</p> <p>14 A. Yes.</p> <p>15 Q. And then there's Tier 2 and 3 later on?</p> <p>16 A. Could have read this. Right --</p> <p>17 Q. In Tier 1 -- and I appreciate the response</p> <p>18 that you gave, but Tier 1 seems to reflect what you had</p> <p>19 just described; correct?</p> <p>20 A. Yes.</p> <p>21 Q. In other words, Mallinckrodt was trying to</p> <p>22 design an SOM program that would focus on oxy 15s and</p> <p>23 oxy 30s; correct?</p> <p>24 A. Correct.</p>	<p style="text-align: right;">Page 188</p> <p>1 algorithm designed to restrict increases over time that</p> <p>2 will apply to orders from all other customers of SKUs</p> <p>3 identified by DEA as particularly subject to diversion</p> <p>4 and abuse.</p> <p>5 Did I read that correctly?</p> <p>6 A. Yes.</p> <p>7 Q. Do you know whether or not that particular</p> <p>8 tier was ever utilized in connection with</p> <p>9 Mallinckrodt's SOM program?</p> <p>10 A. I mean, the tier continues right on the</p> <p>11 second page. So if I could just --</p> <p>12 Q. Fair enough. And take your time to read</p> <p>13 that. I'll let you review that.</p> <p>14 A. All right, thanks. Okay. So can you</p> <p>15 repeat your question now?</p> <p>16 Q. Sure. Was the description contained in</p> <p>17 this particular exhibit regarding Tier 2 ever utilized</p> <p>18 or memorialized in a Mallinckrodt SOM policy?</p> <p>19 MR. O'CONNOR: Objection to form.</p> <p>20 A. I believe, yes.</p> <p>21 BY MR. KO:</p> <p>22 Q. And approximately when was that?</p> <p>23 A. The same time frame.</p> <p>24 Q. And was it --</p>
<p style="text-align: right;">Page 187</p> <p>1 MR. O'CONNOR: Objection to form.</p> <p>2 A. Correct.</p> <p>3 BY MR. KO:</p> <p>4 Q. And in particular -- strike that.</p> <p>5 In addition, Mallinckrodt was also trying</p> <p>6 to design an SOM program that was specifically focused</p> <p>7 on ABC, Cardinal, McKesson, and H.D. Smith; correct?</p> <p>8 MR. O'CONNOR: Objection to form.</p> <p>9 A. Yes.</p> <p>10 BY MR. KO:</p> <p>11 Q. And earlier you had said the big three</p> <p>12 plus H.D. Smith. These are the four distributors that</p> <p>13 were customers of Mallinckrodt that it was focusing on</p> <p>14 for purposes of its SOM program at this time; correct?</p> <p>15 A. Correct.</p> <p>16 MR. O'CONNOR: Objection to form.</p> <p>17 BY MR. KO:</p> <p>18 Q. And in your description that you gave a</p> <p>19 moment ago regarding Tiers 2 and 3, that seems to be a</p> <p>20 little different than what's referred to in this</p> <p>21 particular document.</p> <p>22 A. Okay.</p> <p>23 Q. And here -- in particular, this document</p> <p>24 indicates that Tier 2 is, quote, an enhanced standard</p>	<p style="text-align: right;">Page 189</p> <p>1 A. Oh. December 2011. Yeah, so again, the</p> <p>2 date on this is December 2011, and my understanding is</p> <p>3 that this procedure went into play in March of 2012.</p> <p>4 Q. And in fact, the procedure outlined here</p> <p>5 with respect to Tier 2 and Tier 3 -- is it your</p> <p>6 testimony that those tiers were in fact utilized as of</p> <p>7 March of 2012?</p> <p>8 A. Yes.</p> <p>9 Q. You can set that document aside. I'm</p> <p>10 going to hand you what's just been marked as Gillies</p> <p>11 Exhibit 20.</p> <p>12 [Exhibit Mallinckrodt-Gillies-020</p> <p>13 marked for identification.]</p> <p>14 Q. And this document ends in Bates 2357607,</p> <p>15 and it is titled identification and an investigation of</p> <p>16 unusual orders of controlled substances and reports of</p> <p>17 suspicious orders of controlled substances. Do you see</p> <p>18 that?</p> <p>19 A. Yes.</p> <p>20 Q. There's no date on this particular</p> <p>21 document, but there is a reference in the top</p> <p>22 right-hand corner that says that it's new. Do you see</p> <p>23 that?</p> <p>24 A. I do.</p>

<p style="text-align: right;">Page 190</p> <p>1 Q. And I know you said earlier that you've 2 reviewed some SOM policies in preparation for this 3 deposition. 4 Do you recall reviewing this SOM policy? 5 A. I believe I did. 6 Q. And is this the policy -- so a moment ago 7 we were talking about the unusual order system, the 8 target date for that system to go live as of March of 9 2012. 10 Does this particular policy reflect the 11 new revised system that Mallinckrodt implemented at 12 that time? 13 MR. O'CONNOR: Objection to form. 14 A. I believe it did. 15 BY MR. KO: 16 Q. And in this particular document there are 17 definitions made to unusual order and suspicious order. 18 Do you see that? 19 A. Yes. 20 Q. And similar to some of the prior policies 21 that we were discussing earlier today that first 22 determined whether an order was peculiar and then 23 subsequently analyzed for whether or not the order was 24 suspicious, here we have a multitiered approach as well</p>	<p style="text-align: right;">Page 192</p> <p>1 A. That's my understanding. 2 Q. We can set that one aside. I'm going to 3 hand you now a copy of what will be marked as Gillies 4 Exhibit 21, which is a cover e-mail from Eileen to 5 Karen Harper dated September 20th, 2012, together with 6 an attachment that begins on Bates 7728782. 7 [Exhibit Mallinckrodt-Gillies-021 8 marked for identification.] 9 Q. So before -- we can look at the cover 10 e-mail in a moment, but looking at the policy itself, 11 this appears to be another written policy of 12 Mallinckrodt's SOM program; is that correct? 13 A. Yes. 14 Q. And there's no date, similar to the one we 15 just looked at, but the cover e-mail for this 16 particular attachment is from September of 2012; 17 correct? 18 A. Yes. 19 Q. So in September of 2012 Mallinckrodt is 20 making revisions to its SOM policy; correct? 21 A. Correct. 22 Q. And in the definitions section, there 23 is -- you see that there is a reference to Tiers 1 and 24 2 but not Tier 3?</p>
<p style="text-align: right;">Page 191</p> <p>1 that distinguishes between an unusual order and a 2 suspicious order; correct? 3 MR. O'CONNOR: Objection to form. 4 A. Yes. 5 BY MR. KO: 6 Q. And an unusual order is one -- well, let 7 me read it so that the record is clear. 8 An unusual order. An order received by 9 Mallinckrodt directly from a customer for a Schedule II 10 through V controlled substance product which exceeds 11 the internal limit set by the application of the 12 three-tiered system of specifically-created algorithms 13 defined in this policy. 14 Did I read that correctly? 15 A. Yes. 16 Q. And that three-tiered system is defined 17 later on in 4.3 through 4.5 of the definitions, 18 correct, on the first page? 19 A. Oh. Okay. Yes. 20 Q. So in other words, if through analysis of 21 Tiers 1 through 3 an order is triggered as being 22 unusual, it would warrant further investigation to 23 determine whether or not an order was suspicious 24 sufficient to notify the DEA; correct?</p>	<p style="text-align: right;">Page 193</p> <p>1 A. Correct. 2 Q. And so earlier when we had discussed the 3 period of time in which there was a three-tiered 4 structure and it moved back to a two-tiered structure, 5 is it your recollection that by September of 2012 6 Mallinckrodt had a two-tiered structure to identify 7 whether an order was unusual? 8 A. Yes. 9 Q. And so is it fair to say from March of 10 2012 through September of 2012, Mallinckrodt utilized a 11 three-tiered structure to analyze whether an order was 12 unusual? 13 A. Yes. 14 Q. And after moving back to two tiers to 15 define an unusual order, has there been any point in 16 time from 2012 to present in which Mallinckrodt 17 utilized anything other than a two-tiered structure to 18 determine whether or not an order was unusual? 19 MR. O'CONNOR: Objection to form. 20 A. Not that I'm aware of. 21 BY MR. KO: 22 Q. And if we examine the -- this particular 23 draft, there is no reference made to suspicious order. 24 Do you see that?</p>

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1 A. Well, I mean, under 4.1 it says unusual
2 orders will be reported to DEA upon discovery as
3 suspicious orders in accordance with the CFR.
4 Q. Okay. Fair enough. I guess I meant to
5 say in the prior version there was a clear definition
6 of an unusual order and a clear definition of
7 suspicious order; correct?
8 A. Okay. Yes.
9 Q. And in this version the definition for
10 suspicious order is removed; correct?
11 MR. O'CONNOR: Objection to form.
12 A. Correct. I do not see that definition.
13 BY MR. KO:
14 Q. And in the two-tiered system that now
15 comprises the unusual orders algorithm, do you have an
16 understanding of why that change was made from three
17 tiers back down to two?
18 A. It was my understanding that the third
19 tier was incorporated into the Tier 2.
20 Q. And so in other words -- well, how was it
21 incorporated?
22 A. It's my understanding that there were few,
23 if any, that fell into that Tier 3 category, and that
24 if it were to -- if that category or that instance were

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1 to happen, it would now be picked up by Tier 2.
2 Q. I see. And so when you say that there
3 were few, if any, that fell into the Tier 3 category,
4 that was the Tier 3 category that was in existence from
5 March of 2012 through September of 2012?
6 A. That's right. So this would have been an
7 enhancement to that based on the experience over the
8 previous six months.
9 Q. And with respect to Tier 2, the standard
10 algorithm is referenced as follows. [REDACTED] the average
11 number of orders of a product during the previous 18
12 months by the customer, and, B, [REDACTED] the average volume
13 of product ordered during the previous 18 months by the
14 customer.
15 Did I read that correctly?
16 A. Yes.
17 Q. And so what's different about this
18 particular algorithm is that there's an increase in the
19 time period; is that correct?
20 A. Yes.
21 Q. From 12 months to 18 months?
22 A. Correct.
23 Q. And there's -- what I want to understand
24 and make sure I have correct is that there's reference

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1 made to both the average number of orders and the
2 average number of volume. Do you see that?
3 A. Yes.
4 Q. So in order to trigger this algorithm
5 referenced in Tier 2, did the order have to be both
6 [REDACTED] the average number of orders and [REDACTED]
7 [REDACTED] the average of volume in order to trigger the
8 unusual orders algorithm set forth in this policy?
9 MR. O'CONNOR: Objection to form.
10 A. So the way I read 4.3, yes.
11 BY MR. KO:
12 Q. And prior -- it's fair to say that prior
13 to two thousand -- September of 2012, Mallinckrodt did
14 not utilize or did not investigate into the total
15 average volume of a product that was ordered during a
16 prior time period?
17 MR. O'CONNOR: Objection to form.
18 A. I'm not aware of that.
19 BY MR. KO:
20 Q. Did you ever see reference to any written
21 SOM policy prior to September of 2012 that incorporated
22 historical overview of the average volume of a product
23 ordered by a particular customer?
24 MR. O'CONNOR: Objection to form.

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1 A. Not that I can recall.
2 BY MR. KO:
3 Q. And in this document, the Tier 1 sets
4 forth a tier devoted to oxy 15s and oxy 30s by certain
5 distributors; correct?
6 A. Yes.
7 Q. And --
8 A. Similar to the previous.
9 Q. Right. And there was -- well, explain to
10 the court why it was important for Mallinckrodt to
11 focus on oxy 15s and oxy 30s and set that apart for
12 purposes of its SOM policy.
13 MR. O'CONNOR: Objection to form.
14 A. These were our largest customers.
15 BY MR. KO:
16 Q. And by largest customers you mean ABC,
17 McKesson, Cardinal, and H.D. Smith?
18 A. Yes.
19 Q. And what about with respect to oxy 15s and
20 oxy 30s? Were -- was that the primary -- or did those
21 prescription opioids reflect the majority of drugs
22 manufactured by Mallinckrodt during this time?
23 A. I don't know that to be the case.
24 Q. Is it accurate to state that following the

<p style="text-align: right;">Page 198</p> <p>1 August 2011 meeting that we had discussed before with 2 the DEA, the DEA was particularly concerned about 3 diversion of oxy 15s and oxy 30s of -- manufactured by 4 Mallinckrodt; correct? 5 MR. O'CONNOR: Objection to form. 6 A. I don't know that that characterizes the 7 meeting accurately. From my recollection, they were 8 telling us that they were concerned about oxy 15s and 9 oxy 30s, and I don't know that they qualified it saying 10 that it was just Mallinckrodt oxy 15s or 30s. 11 BY MR. KO: 12 Q. Fair enough. Mallinckrodt manufactures 13 oxy 15s and oxy 30s; correct? 14 A. That's correct. 15 Q. And Mallinckrodt has been manufacturing 16 those products for -- since at least the mid-2000s; 17 correct? 18 A. That's my understanding. 19 Q. And when you said a moment ago that -- 20 when you were talking about your recollection of what 21 the DEA said, that was through your review of 22 documents; correct? 23 A. Correct. 24 Q. In other words, I mean, you weren't at the</p>	<p style="text-align: right;">Page 200</p> <p>1 as particularly subject to diversion and abuse, end 2 quote. 3 Did I read that correctly? 4 A. Yes. 5 Q. Were there any other drugs that the -- 6 prior to 2012 that the DEA had informed Mallinckrodt of 7 being subject to diversion and abuse? 8 MR. O'CONNOR: Objection to form. 9 A. Not that I'm aware of. 10 BY MR. KO: 11 Q. Do you know whether or not the DEA had 12 informed Mallinckrodt that the methadone that it was 13 manufacturing was subject to diversion and abuse? 14 MR. O'CONNOR: Objection to form. 15 A. No. 16 BY MR. KO: 17 Q. You have no knowledge of that, or you 18 believe -- 19 A. I'm not aware of that. 20 Q. You're not aware of that? Okay. In 21 addition to oxy 15s and oxy 30s, Mallinckrodt 22 manufactured other prescription opioids; correct? 23 A. Correct. 24 Q. Including from the hydrocodone and</p>
<p style="text-align: right;">Page 199</p> <p>1 meeting? 2 A. I was not. 3 Q. That predates your -- 4 A. It does. 5 Q. -- employment with Mallinckrodt; correct? 6 A. Correct. 7 Q. And so going back to this document, there 8 is obviously a specific reference made to oxy 15s and 9 oxy 30s; correct? 10 A. Yes. 11 Q. And so why was it the case that 12 Mallinckrodt had designated a specific tier in its SOM 13 policy for oxy 15s and oxy 30s? 14 A. As we had previously in the policies, I 15 believe it came from the discussion with DEA. 16 Q. So as a result of DEA's -- is it fair to 17 say as a result of DEA's increased scrutiny on oxy 15s 18 and oxy 30s, Mallinckrodt decided to designate those 19 particular drugs as part of its SOM written policy? 20 MR. O'CONNOR: Objection to form. 21 A. As a separate tier, yes. 22 BY MR. KO: 23 Q. And this particular document indicates 24 that, quote, these products have been identified by DEA</p>	<p style="text-align: right;">Page 201</p> <p>1 hydromorphone molecules? 2 A. Yes. 3 Q. And do you recall prior to 2012 whether or 4 not the DEA had any communications with Mallinckrodt 5 regarding whether or not these products were subject to 6 diversion and abuse? 7 A. No. 8 Q. No, you don't have any recollection of 9 those communications? 10 A. I do not. Yes. 11 Q. But you don't know whether or not they 12 happened one way or the other? 13 A. I have no recollection of that being 14 discussed -- 15 Q. Got it. 16 A. -- prior to this time frame. 17 Q. And what about following September 2012? 18 Did Mallinckrodt have any discussions with DEA 19 regarding the diversion and abuse potential of any 20 hydrocodone or hydromorphone products? 21 A. I became aware of that. 22 Q. During what time period? 23 A. Post-September 2012 time frame. 24 Q. And when approximately?</p>

<p style="text-align: right;">Page 202</p> <p>1 A. Sometime after September of 2012. So 2 October, November time frame. Late 2012. 3 Q. So shortly after? 4 A. Shortly after. Yeah. 5 Q. I see. So fair to say that in the fall of 6 2012, Mallinckrodt communicated with the DEA regarding 7 the diversion and abuse potential of its hydrocodone 8 and hydromorphone products? 9 A. Again, not -- it wasn't Mallinckrodt. It 10 was just you need to start looking at hydrocodone too. 11 So they didn't say we have a problem with 12 Mallinckrodt hydrocodone; it's we're seeing a problem 13 with hydrocodone now too. 14 Q. I understand. 15 A. Okay. I just want to make sure I'm 16 understanding your question, because -- 17 Q. Sure. And that's a fair clarification of 18 the record. 19 A. Okay. 20 Q. Mallinckrodt did in fact manufacture 21 certain hydrocodone and hydromorphone products; 22 correct? 23 A. Correct. 24 Q. And it's your testimony today -- is it an</p>	<p style="text-align: right;">Page 204</p> <p>1 Q. And do you recall for what time period 2 these discussions covered? 3 A. So my recollection is late 2012 into early 4 2013. 5 Q. And do you recall any discussions with the 6 DEA regarding the abuse and diversion potential of 7 hydrocodone and hydromorphone following early 2013? 8 A. I have no recollection of any specific 9 discussions on that. 10 Q. Here is a copy of what's going to be 11 marked as Gillies Exhibit 22. 12 [Exhibit Mallinckrodt-Gillies-022 13 marked for identification.] 14 Q. And for the record, this document ends in 15 Bates 7476261, and it is entitled identification 16 investigation reports of controlled substances 17 suspicious orders, effective date October 18th, 2012. 18 Do you recall reviewing this document in 19 preparation for this deposition today? 20 A. No. 21 Q. For this particular -- let me take a step 22 back. 23 Did you review any written policies 24 regarding Mallinckrodt's SOM procedure in preparation</p>
<p style="text-align: right;">Page 203</p> <p>1 accurate reflection of your testimony that Mallinckrodt 2 communicated with the DEA regarding the abuse and 3 diversion potential of hydrocodone and hydromorphone 4 products in general? 5 A. Yes. 6 Q. You can set that one aside. 7 And by the way, with respect to 8 hydrocodone and hydromorphone, did those discussions 9 about the abuse and diversion potential of those 10 products -- how long did they last? 11 MR. O'CONNOR: Objection to form. 12 A. I don't know what you mean by the timing 13 of that. You mean like a five-minute meeting or over a 14 certain amount of time? 15 BY MR. KO: 16 Q. Yeah. 17 A. So I'm sorry. 18 Q. Fair enough. Did you -- when you began 19 having discussions with the DEA about the hydro -- 20 about the abuse and diversion potential of 21 hydromorphone and hydrocodone, how -- do you recall how 22 many meetings with the DEA Mallinckrodt had on this 23 topic? 24 A. Several, at least.</p>	<p style="text-align: right;">Page 205</p> <p>1 for your deposition today? 2 A. I believe I did. 3 Q. Which ones? 4 MR. O'CONNOR: I'm going to object. 5 Again, we're not going to get into the specific 6 selection of documents on the basis of work product and 7 attorney-client privilege. 8 BY MR. KO: 9 Q. Did review of those documents help refresh 10 your recollection at all as to Mallinckrodt's SOM 11 policies over time? 12 MR. O'CONNOR: Objection to form. 13 Objection to the extent you're asking him to confirm 14 which documents. 15 BY MR. KO: 16 Q. And I'm not. I'm simply asking whether or 17 not review of certain SOM written policies that you 18 claim you have reviewed help refresh your recollection 19 regarding SO -- Mallinckrodt's SOM system. 20 A. Yes. 21 Q. And which specific documents did you 22 review? 23 MR. O'CONNOR: Again, same objection. 24 Instruct the witness not to answer.</p>

<p style="text-align: right;">Page 206</p> <p>1 MR. KO: Okay. Well, and I'll note for</p> <p>2 the record that that's an improper instruction, because</p> <p>3 anything that refresh the witness's recollection in</p> <p>4 terms of preparing for this deposition certainly is not</p> <p>5 subject to the privilege.</p> <p>6 MR. O'CONNOR: We can address that issue</p> <p>7 later.</p> <p>8 BY MR. KO:</p> <p>9 Q. So just so the record is clear, Mr.</p> <p>10 Gillies, you did review specific written policies</p> <p>11 regarding Mallinckrodt's SOM program; correct?</p> <p>12 A. Yes.</p> <p>13 Q. And do you recall approximately how many</p> <p>14 you reviewed?</p> <p>15 A. I do not.</p> <p>16 Q. Was it more than five?</p> <p>17 A. No.</p> <p>18 Q. So you reviewed -- was it more than three?</p> <p>19 A. I don't know how many I did, but I don't</p> <p>20 believe it was more than five.</p> <p>21 Q. And for what time period did those</p> <p>22 policies span?</p> <p>23 A. Yeah. I don't recall.</p> <p>24 Q. But you reviewed no more than five written</p>	<p style="text-align: right;">Page 208</p> <p>1 of the questions that I want to ask about this.</p> <p>2 This is -- this document reflects that you</p> <p>3 are part of the SOM leadership team; correct?</p> <p>4 A. Yes.</p> <p>5 Q. And was this the first document that you</p> <p>6 became -- or the first SOM policy that you became</p> <p>7 involved in after you joined Mallinckrodt?</p> <p>8 MR. O'CONNOR: Objection to form.</p> <p>9 A. I don't think so.</p> <p>10 BY MR. KO:</p> <p>11 Q. So prior to this date you had reviewed</p> <p>12 some other drafts or policies; correct?</p> <p>13 A. Yes.</p> <p>14 Q. And for this particular version of the SOM</p> <p>15 policy, there is a definition of suspicious order. Do</p> <p>16 you see that -- in 4.1?</p> <p>17 A. Yes.</p> <p>18 Q. And there's no -- the definition of an</p> <p>19 unusual order is removed; correct?</p> <p>20 A. Yes.</p> <p>21 MR. O'CONNOR: Objection to form.</p> <p>22 BY MR. KO:</p> <p>23 Q. But regardless of the names of the</p> <p>24 definition, the two-tiered structure for determining</p>
<p style="text-align: right;">Page 207</p> <p>1 policies for a time period you don't recall, is that</p> <p>2 accurate, in connection with preparing for this</p> <p>3 deposition?</p> <p>4 A. Correct.</p> <p>5 Q. And you don't recall reviewing -- as we</p> <p>6 discussed earlier, you don't recall reviewing this</p> <p>7 particular one; correct?</p> <p>8 A. During my preparation for this deposition?</p> <p>9 Q. Yes.</p> <p>10 A. No.</p> <p>11 Q. How about outside of the preparation for</p> <p>12 the deposition, do you recall ever seeing any</p> <p>13 Mallinckrodt written SOM policies?</p> <p>14 A. Yes.</p> <p>15 Q. Which ones?</p> <p>16 A. I recall this one.</p> <p>17 Q. You do recall reviewing this one, then,</p> <p>18 but not --</p> <p>19 A. But now I got the clarification, it wasn't</p> <p>20 for this purpose.</p> <p>21 Q. And you recall --</p> <p>22 A. And I was employed by Mallinckrodt at this</p> <p>23 time.</p> <p>24 Q. Okay. We'll get -- that segues into a few</p>	<p style="text-align: right;">Page 209</p> <p>1 whether or not an order may potentially be suspicious</p> <p>2 remains the same from the prior version we looked at;</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. And going back to the SOM leadership team,</p> <p>6 we see that it's comprised of Don Lohman, you, John</p> <p>7 Gillies, Gail Tetzlaff, who you I believe referred to</p> <p>8 before, and Karen Harper.</p> <p>9 A. Correct.</p> <p>10 Q. Do you see that?</p> <p>11 A. Uh-huh.</p> <p>12 Q. Was that the same leadership structure</p> <p>13 that was in place when you joined Mallinckrodt in June</p> <p>14 of 2012?</p> <p>15 MR. O'CONNOR: Objection to form.</p> <p>16 A. Yes.</p> <p>17 BY MR. KO:</p> <p>18 Q. And I believe you -- again, you referred</p> <p>19 to Gail before, and you referred to the SOM leadership</p> <p>20 team, but I want to understand clearly whether or not</p> <p>21 this -- well, strike that.</p> <p>22 Since 2012 to present, has the composition</p> <p>23 of the SOM leadership team changed at all?</p> <p>24 A. Yes.</p>

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1 Q. In what way has it changed?

2 A. I believe we have an additional member or

3 two to the leadership team.

4 Q. And who are they?

5 A. I believe Jason Tilly is part of the

6 leadership team, and I believe there's one other party.

7 But I -- sorry. I can't remember their name.

8 Q. Okay. Fair enough. And do you recall

9 when Mr. Tilly was added to the SOM leadership team?

10 A. I don't recall the time frame.

11 Q. And how about the other individual who you

12 don't recall? Do you have any understanding of when

13 she or he was added to the team?

14 A. I believe we added another member sometime

15 in late 2018.

16 Q. So recently?

17 A. Recently. Uh-huh.

18 Q. So fair to say from 2012 through 2018 the

19 composition of the SOM leadership team were the four

20 individuals listed here and Mr. Tilly at some point?

21 MR. O'CONNOR: Object to form.

22 A. Yes.

23 BY MR. KO:

24 Q. You can set that aside. I'm now going to

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1 hand you a copy of what will be marked as -- or what

2 has been marked as Gillies Exhibit 23.

3 [Exhibit Mallinckrodt-Gillies-023

4 marked for identification.]

5 Q. For the record, this ends in Bates

6 5620500.

7 And this is a document titled

8 identification, investigation, and reports of

9 controlled substances suspicious orders, effective date

10 November 1st, 2012. Do you see that?

11 A. Yes.

12 Q. And it appears to supersede the prior

13 version that we just looked at from October 18th, 2012?

14 A. Yes.

15 Q. And I just have a quick question on this

16 document.

17 A. Uh-huh.

18 Q. Here in Tier 2, there's an adjustment made

19 to the algorithm. Is that accurate?

20 A. Yes.

21 Q. And the specific adjustment that is made

22 is from -- down from [REDACTED] to [REDACTED] of the

23 previous 18-month average number of orders in volume;

24 correct?

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1 A. Correct.

2 Q. And why was this change made?

3 A. An enhancement to the program. So we had

4 the [REDACTED] at one point, then we had the [REDACTED], and through

5 time we enhanced the program again, and it's always

6 undergoing review, and at this point a change was made

7 to 2.5.

8 Q. And it's my understanding that the -- is

9 it the case that the [REDACTED] [REDACTED]

10 [REDACTED] order in volume is the current system

11 in place as well?

12 A. That's correct.

13 Q. So is it accurate to say that from

14 November 2012 to present the algorithm to detect

15 suspicious order has not changed?

16 MR. O'CONNOR: Objection to form.

17 A. That's my understanding.

18 BY MR. KO:

19 Q. And just so the record is clear, the -- in

20 this particular document, the special attention on oxy

21 15s and 30s distributed by Mallinckrodt's major

22 customers remains to be in the policy; correct?

23 A. Correct.

24 Q. And in the current iteration of the SOM

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1 policy, does that Tier 1 still exist?

2 A. In this policy?

3 Q. I'm sorry.

4 A. I'm sorry.

5 Q. Yeah, I'm sorry if I confused you. In the

6 current iteration of Mallinckrodt's SOM policy today,

7 is there still special attention given to oxy 15s and

8 oxy 30s?

9 MR. O'CONNOR: Objection to form.

10 A. Yes.

11 BY MR. KO:

12 Q. And is there still special attention given

13 to oxy 15s and 30s distributed by ABC, McKesson,

14 Cardinal, and H.D. Smith?

15 MR. O'CONNOR: Objection to form.

16 A. Yes.

17 BY MR. KO:

18 Q. Okay. Thank you. You can set that aside.

19 MR. O'CONNOR: Should we take a break?

20 MR. KO: Yeah, sure.

21 THE VIDEOGRAPHER: We are going off the

22 record at 2:46 PM.

23 [A brief recess was taken.]

24 THE VIDEOGRAPHER: We are back on the

<p style="text-align: right;">Page 214</p> <p>1 record at 3:06 PM. 2 BY MR. KO: 3 Q. Welcome back from the break. This is the 4 home stretch, at least with respect to my questioning, 5 Mr. Gillies, so thank you for your patience today. 6 A. Yes. 7 Q. I'm going to hand you -- or you have in 8 front of you a copy of what's been marked as Gillies 9 Exhibit -- 10 MS. GAFFNEY: 24. 11 BY MR. KO: 12 Q. -- 24. And for the record, this document 13 ends in Bates 511246, and it is titled identification, 14 investigation, and reports of controlled substances 15 suspicious orders, and the effective date is August 16 17th, 2015, in the top right-hand corner. 17 Do you see that, Mr. Gillies? 18 [Exhibit Mallinckrodt-Gillies-024 19 marked for identification.] 20 A. Yes. 21 Q. Did you review this particular policy in 22 preparation for your deposition today? 23 A. No. 24 Q. And this particular document seems to</p>	<p style="text-align: right;">Page 216</p> <p>1 Q. And no more than that additional one; 2 correct? 3 In other words, have you seen -- outside 4 of the document that postdates August 17th, 2015, have 5 you seen any other additional SOM written policies 6 other than that version? 7 MR. O'CONNOR: Objection to form. 8 A. My recollection is that there might be two 9 after this. 10 BY MR. KO: 11 Q. But you don't have an understanding of 12 when those effective -- when the effective dates of 13 those written policies were; correct? 14 A. That's correct. 15 Q. Now, turning to this particular document, 16 I just have a few questions on this. 17 A. Yes. 18 Q. Here we have an identification of who is 19 on the SOM team but not any names. Do you see that in 20 Section 4.5? 21 A. I do. 22 Q. And there is also an indication of a 23 senior data analyst being part of the team. 24 A. Yes.</p>
<p style="text-align: right;">Page 215</p> <p>1 indicate that it's superseding a prior version dated 2 March 7th, 2013. Do you see that? 3 A. Yes. 4 Q. Do you recall whether or not you reviewed 5 the March 7th, 2013, SOM policy? 6 A. I don't recall as we sit here. 7 Q. And do you know whether or not 8 Mallinckrodt's current SOM policy is -- well, strike 9 that. 10 Do you have any understanding of whether 11 or not this version that we're looking at is 12 Mallinckrodt's current SOM written policy? 13 A. I do not. 14 Q. Do you know -- have you seen recently 15 Mallinckrodt's written SOM policy? 16 A. I believe I've seen one more recent than 17 this. 18 Q. And do you know what approximate effective 19 date that particular document has? 20 A. I do not. 21 Q. But it's your understanding that there may 22 be one that postdates August 17th, 2015; is that 23 correct? 24 A. I believe there is.</p>	<p style="text-align: right;">Page 217</p> <p>1 Q. You see that? And does that refresh your 2 recollection at all that there were, in addition to Mr. 3 Tilly and perhaps the other individual who you don't 4 recall was added in 2018, does that refresh your 5 recollection as to an additional member of the SOM team 6 as of 2015? 7 A. Yes. 8 Q. And who was this particular individual? 9 A. Jen Buist. 10 Q. And she currently is still with 11 Mallinckrodt; correct? 12 A. No. 13 Q. Did she recently leave Mallinckrodt? 14 A. No. 15 Q. When did she leave Mallinckrodt? 16 A. Several years ago. 17 Q. Do you have an approximate time -- do you 18 have a general understanding of the approximate time 19 period in which she left? 20 A. 2015 is my recollection. 21 Q. So maybe around the time of this -- 22 effective date of this document? 23 MR. O'CONNOR: Objection to form. 24 A. I don't know the exact time.</p>

<p style="text-align: right;">Page 218</p> <p>1 BY MR. KO:</p> <p>2 Q. Fair enough. Who took over or who was</p> <p>3 Jennifer's predecessor?</p> <p>4 A. I don't know that she had had a</p> <p>5 predecessor, and I don't know that this position --</p> <p>6 that this position exists. So --</p> <p>7 Q. In other words, you don't know if -- prior</p> <p>8 to Jennifer being the SOM data analyst and being on the</p> <p>9 SOM leadership team, that position was not in existence</p> <p>10 at Mallinckrodt? Is that your testimony?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. I'm sorry. Your question is confusing me,</p> <p>13 because you said the predecessor, right, to Jen? I'm</p> <p>14 sorry. Go ahead.</p> <p>15 BY MR. KO:</p> <p>16 Q. Yeah. No, and I can see I was confusing</p> <p>17 because I was initially going to ask who took over for</p> <p>18 Jen, but I also wanted to get an understanding --</p> <p>19 A. Okay.</p> <p>20 Q. -- of who was in place, if anyone, before</p> <p>21 Jen.</p> <p>22 A. Yeah.</p> <p>23 Q. So I apologize. So the record is clear,</p> <p>24 was there a senior data analyst for the SOM program</p>	<p style="text-align: right;">Page 220</p> <p>1 Q. Got it. And who is that individual that</p> <p>2 plays the role of the new position that you don't</p> <p>3 recall the title of?</p> <p>4 A. Yes. It's a -- I believe I identified her</p> <p>5 earlier today, but I only recall her first name.</p> <p>6 Rochelle.</p> <p>7 Q. I see. And generally speaking, what are</p> <p>8 her responsibilities?</p> <p>9 A. One of her responsibilities is going to be</p> <p>10 reviewing any chargeback data that we may have on</p> <p>11 pharmacies of concern, doing some record reviews, and</p> <p>12 there's other things in her job description, but I</p> <p>13 don't recall them all, so -- but she is part of the SOM</p> <p>14 team.</p> <p>15 Q. With respect to the chargebacks, what is</p> <p>16 your understanding of what the chargeback data</p> <p>17 consisted of or consists of today?</p> <p>18 MR. O'CONNOR: Objection to form and</p> <p>19 scope.</p> <p>20 A. It would be pharmacy, name, distributor</p> <p>21 that distributes to the pharmacy, and what Mallinckrodt</p> <p>22 product is involved in the chargeback.</p> <p>23 BY MR. KO:</p> <p>24 Q. Is it accurate to also say that the</p>
<p style="text-align: right;">Page 219</p> <p>1 prior to Jennifer?</p> <p>2 A. So -- I don't believe so, but Jen's time</p> <p>3 goes back to 2011.</p> <p>4 Q. And what were Jennifer's roles and</p> <p>5 responsibilities as a senior data analyst for the SOM</p> <p>6 team?</p> <p>7 A. She reviewed the peculiar, unusual reports</p> <p>8 that were produced twice a day. She was one of the</p> <p>9 analysts that reviewed those.</p> <p>10 Q. And the purpose of her review was to</p> <p>11 determine whether or not the peculiar or unusual order</p> <p>12 would be suspicious sufficient to notify the DEA;</p> <p>13 correct?</p> <p>14 A. Correct.</p> <p>15 Q. And after Jennifer left in the 2015 time</p> <p>16 period, who took over for her as a senior data analyst?</p> <p>17 A. I think that position went away and a new</p> <p>18 position was created.</p> <p>19 Q. I see. And what was that new position?</p> <p>20 A. I don't recall what the new position is.</p> <p>21 Q. Does that new position currently exist as</p> <p>22 part of the SOM leadership team that you're a part of?</p> <p>23 A. Part of the SOM team. I don't believe</p> <p>24 part of the leadership team.</p>	<p style="text-align: right;">Page 221</p> <p>1 chargeback data reveals a -- the pharmacy or clinic</p> <p>2 that purchases the Mallinckrodt controlled substance or</p> <p>3 Mallinckrodt pharmaceutical from a distributor?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. Yes.</p> <p>6 BY MR. KO:</p> <p>7 Q. And Mallinckrodt is currently utilizing</p> <p>8 that chargeback data in connection with its SOM</p> <p>9 program; correct?</p> <p>10 A. Correct.</p> <p>11 Q. And Mallinckrodt has in the past utilized</p> <p>12 the chargeback data in connection with its SOM program;</p> <p>13 correct?</p> <p>14 A. Correct.</p> <p>15 Q. And I believe Mallinckrodt began utilizing</p> <p>16 this information as early as 2010. Is that accurate to</p> <p>17 state?</p> <p>18 A. Yes.</p> <p>19 Q. And Mallinckrodt has been paying</p> <p>20 distributors chargeback amounts pursuant to agreements</p> <p>21 it has with the distributors for as long as -- well,</p> <p>22 strike that.</p> <p>23 Do you have an understanding of when</p> <p>24 Mallinckrodt first entered into an agreement with a</p>

<p style="text-align: right;">Page 222</p> <p>1 distributor whereby Mallinckrodt would pay chargeback</p> <p>2 amounts to its customers?</p> <p>3 MR. O'CONNOR: Objection to scope.</p> <p>4 A. No.</p> <p>5 BY MR. KO:</p> <p>6 Q. Do you have any recollection of whether</p> <p>7 that was before or after 2005?</p> <p>8 MR. O'CONNOR: Same objection.</p> <p>9 A. No.</p> <p>10 BY MR. KO:</p> <p>11 Q. Turning back to this document. Here we</p> <p>12 have -- I know we have talked about the difference</p> <p>13 between two tiers and three tiers.</p> <p>14 A. Uh-huh.</p> <p>15 Q. But here we have a reference to three</p> <p>16 tiers. Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. And I know -- so earlier you said that you</p> <p>19 believe that beginning in 2012 Mallinckrodt had</p> <p>20 utilized just the two-tier system; correct?</p> <p>21 A. Correct.</p> <p>22 Q. So does this refresh your recollection at</p> <p>23 all that Mallinckrodt actually moved back to a</p> <p>24 three-tier system at some point in time?</p>	<p style="text-align: right;">Page 224</p> <p>1 exist in any way in Mallinckrodt's SOM program today?</p> <p>2 A. I don't believe it does.</p> <p>3 Q. So would it be fair to say that the</p> <p>4 current iteration of Mallinckrodt's SOM program</p> <p>5 contains the first two tiers mentioned in this</p> <p>6 document?</p> <p>7 A. Yes.</p> <p>8 Q. So at some point in time the third tier</p> <p>9 was removed, but you don't recall when?</p> <p>10 A. Correct.</p> <p>11 Q. All right. You can set that one aside.</p> <p>12 So your counsel just received his wish, and probably</p> <p>13 yours too. That was the last policy that we're going</p> <p>14 to go over today.</p> <p>15 A. I can feel the air-conditioning kicking on</p> <p>16 already.</p> <p>17 Q. I'm going to hand you a copy of what has</p> <p>18 been marked as Gillies Exhibit 25.</p> <p>19 [Exhibit Mallinckrodt-Gillies-025</p> <p>20 marked for identification.]</p> <p>21 Q. And I just have a few quick questions</p> <p>22 about this.</p> <p>23 For the record, this is an e-mail dated</p> <p>24 March 10th, 2009, from Wendy "Slab" to Karen Harper,</p>
<p style="text-align: right;">Page 223</p> <p>1 A. I see it there. My recollection was we</p> <p>2 were -- had two tiers, but there is a third tier listed</p> <p>3 here.</p> <p>4 Q. And currently as it stands now, however,</p> <p>5 there is just a two-tier system; correct?</p> <p>6 A. That's my understanding.</p> <p>7 Q. And when did -- how long has</p> <p>8 Mallinckrodt's two-tier system been in effect?</p> <p>9 A. I'm sorry. I don't know. I thought it</p> <p>10 was from September of 2012, so clearly there was a</p> <p>11 change, according to this document.</p> <p>12 Q. Sure. And so it's fair to say that as of</p> <p>13 August 17th, 2015, Mallinckrodt is utilizing a</p> <p>14 three-tier structure to determine whether or not an</p> <p>15 order is suspicious?</p> <p>16 A. That's what it says at this time.</p> <p>17 Q. And with respect to the third tier,</p> <p>18 there's a reference made to a monthly limit placed on a</p> <p>19 customer based on customer bill-to address for a</p> <p>20 particular SKU for a particular amount.</p> <p>21 Did I read that correctly?</p> <p>22 A. Yes.</p> <p>23 Q. And as far as you understand the current</p> <p>24 iteration of Mallinckrodt's SOM program, does that tier</p>	<p style="text-align: right;">Page 225</p> <p>1 ending in Bates 263874, and containing an attachment</p> <p>2 that begins at 875.</p> <p>3 Do you know who Wendy "Slab" is?</p> <p>4 A. I don't recall who she is. And I do</p> <p>5 believe you pronounce it Wendy Slaby.</p> <p>6 Q. Wendy Slaby. Thank you.</p> <p>7 A. Uh-huh.</p> <p>8 Q. This appears to be a flowchart of how a</p> <p>9 peculiar order -- or excuse me.</p> <p>10 This appears to be a flowchart of how a</p> <p>11 suspicious order is identified after it is identified</p> <p>12 as a peculiar order. Is that fair to say?</p> <p>13 A. I'm sorry. Could you say that one more</p> <p>14 time?</p> <p>15 Q. Yeah. It was a bad question. Let me ask</p> <p>16 again.</p> <p>17 Earlier we had discussed the concept of a</p> <p>18 multitiered structure for which Mallinckrodt first</p> <p>19 identified a particular order and then did continued</p> <p>20 analysis to determine whether or not it was suspicious</p> <p>21 sufficient to notify the DEA; correct?</p> <p>22 A. Correct.</p> <p>23 Q. And this document appears to be a</p> <p>24 flowchart reflecting that process. Is that fair to</p>

<p style="text-align: right;">Page 226</p> <p>1 say?</p> <p>2 A. Yes.</p> <p>3 Q. And you don't need to count all the boxes,</p> <p>4 but there appear to be several boxes of analyses that</p> <p>5 Mallinckrodt is undergoing to determine whether or not</p> <p>6 the order should ship or whether or not the order</p> <p>7 should be notified to the DEA. Is that fair to say?</p> <p>8 A. Yes.</p> <p>9 Q. And the date of this e-mail attaching this</p> <p>10 flowchart is from March of 2009; correct?</p> <p>11 A. Correct.</p> <p>12 Q. So at least as of the date of this e-mail,</p> <p>13 this appears to be a flowchart that Mallinckrodt is</p> <p>14 trying to follow to determine whether or not an order</p> <p>15 is suspicious after it is identified as peculiar;</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. And just so I understand clearly, is it</p> <p>19 accurate to state that this analysis only occurs after</p> <p>20 an order is identified as peculiar?</p> <p>21 A. Yes.</p> <p>22 Q. So none of these factors are examined if</p> <p>23 the peculiar order algorithm we've discussed before is</p> <p>24 not triggered; correct?</p>	<p style="text-align: right;">Page 228</p> <p>1 reference made to the filing of a peculiar order report</p> <p>2 with annotation. Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. And I believe that peculiar order</p> <p>5 report -- the intention was to file that report and</p> <p>6 document the reasons for why a CSR manager believed the</p> <p>7 report was suspicious or not. Is that accurate?</p> <p>8 MR. O'CONNOR: Object to form.</p> <p>9 A. No, I think the way you phrased the</p> <p>10 question, my answer would be no.</p> <p>11 BY MR. KO:</p> <p>12 Q. Okay. Do you recall ever seeing any</p> <p>13 peculiar order reports with annotations from customer</p> <p>14 service rep managers in the 2008 or 2012 time period?</p> <p>15 A. No.</p> <p>16 Q. Have you seen any peculiar order reports</p> <p>17 with annotations from any customer service represent</p> <p>18 manager ever in connection with Mallinckrodt's SOM</p> <p>19 policy?</p> <p>20 A. I don't recall seeing any.</p> <p>21 Q. You can actually set that document aside.</p> <p>22 That's all the questions I have on that.</p> <p>23 Now, earlier today we had discussed</p> <p>24 Mallinckrodt's retention of Frank Sapienza and Howard</p>
<p style="text-align: right;">Page 227</p> <p>1 A. Correct.</p> <p>2 Q. And with respect to some of these</p> <p>3 analyses -- for example, the annotate report with</p> <p>4 explanation -- do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. And apparently that was supposed to be</p> <p>7 done by the customer service rep manager who reviews</p> <p>8 the peculiar order report. Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. Do you have any understanding of whether</p> <p>11 or not this annotated report was documented in any way?</p> <p>12 A. I have no recollection of that.</p> <p>13 Q. Do you recall ever seeing any annotated</p> <p>14 reports from CSR managers during the 2008 to 2012 time</p> <p>15 period?</p> <p>16 A. I do not recall that.</p> <p>17 Q. Currently do CSR managers review certain</p> <p>18 orders and annotate any kind of report with an</p> <p>19 explanation for why the order might be suspicious or</p> <p>20 not?</p> <p>21 MR. O'CONNOR: Objection to form.</p> <p>22 A. No.</p> <p>23 BY MR. KO:</p> <p>24 Q. And moving down this flowchart, there is a</p>	<p style="text-align: right;">Page 229</p> <p>1 Davis in connection with its CSA obligations in general</p> <p>2 and its SOM obligations in particular.</p> <p>3 Were there any other individuals or</p> <p>4 entities that Mallinckrodt retained to assist in</p> <p>5 implementing its SOM program?</p> <p>6 A. Yes.</p> <p>7 Q. And who are these individuals or which</p> <p>8 entities would these be?</p> <p>9 A. I'll give you the entity, Buzzeeo.</p> <p>10 Q. And so in addition to Frank Sapienza and</p> <p>11 Howard Davis and the entity Buzzeeo, were there any</p> <p>12 other individuals or entities that Mallinckrodt</p> <p>13 retained in connections with its duties to design and</p> <p>14 implement a suspicious order monitoring program?</p> <p>15 A. Time frame?</p> <p>16 Q. At any time.</p> <p>17 A. Okay. Including up to today?</p> <p>18 Q. Yes.</p> <p>19 A. I believe the answer is yes.</p> <p>20 Q. Okay. And which other entities or</p> <p>21 individuals?</p> <p>22 A. I can't recall the entity, but I believe</p> <p>23 there was at least one more company that we engaged for</p> <p>24 this purpose.</p>

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1 Q. And approximately what time period was
 2 that from?
 3 A. My recollection was the 2016 time frame.
 4 Q. So fairly recently?
 5 A. Yes.
 6 Q. And do you have any -- I know you don't
 7 recall the name of the entity, but do you recall what
 8 they were retained to do?
 9 A. I do not, but it was another former DEA
 10 official.
 11 Q. I see. So it was an individual that was
 12 retained?
 13 A. No, it was a company.
 14 Q. I see.
 15 A. Yeah. But the individual that the company
 16 dealt with was a former DEA official.
 17 Q. Got it. And do you have any recollection
 18 of what they were -- general recollection --
 19 A. I do not.
 20 Q. -- of what they were retained to do?
 21 A. No.
 22 Q. Going back to Buzzeo. When were they
 23 retained, and for approximately how long?
 24 MR. O'CONNOR: I'm going to object to --

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1 Buzzeo was retained in connection with this litigation
 2 in 2018 in connection with suspicious order monitoring,
 3 and so John, I'm going to instruct you not to answer
 4 with respect to anything beyond the fact of the
 5 engagement.
 6 BY MR. KO:
 7 Q. Okay. So can I --
 8 A. Okay.
 9 Q. Can I accept that representation then made
 10 by your counsel? Is it accurate to say that
 11 Mallinckrodt retained Buzzeo in connection with this
 12 litigation in 2018?
 13 A. Okay. Yes.
 14 Q. Apart from the retention of Buzzeo for
 15 purposes of this litigation in 2018, was Buzzeo
 16 retained at any time prior to that by Mallinckrodt in
 17 connection with its SOM responsibilities?
 18 A. Yes.
 19 Q. And when was that?
 20 A. My recollection is that we utilized them
 21 as early as 2012.
 22 Q. And for what purpose?
 23 A. For SOM purposes.
 24 Q. Any specific purpose, or just generally to

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1 advise Mallinckrodt regarding its SOM obligations?
 2 A. Yes.
 3 Q. Well, let me ask again, because I don't
 4 think that was a yes-or-no question. But was -- for
 5 what general purpose did Mallinckrodt retain Buzzeo
 6 for?
 7 A. To assist us in our SOM efforts.
 8 Q. And was there any particular aspect of the
 9 SOM efforts that Buzzeo advised Mallinckrodt on?
 10 A. Yes.
 11 Q. And what were those aspects?
 12 A. Do I have a privilege?
 13 MR. O'CONNOR: I mean, we can go off the
 14 record.
 15 MR. KO: Sure. Let's do it. Sure.
 16 MR. O'CONNOR: Yeah.
 17 MR. KO: We'll go off the record for a
 18 moment.
 19 THE VIDEOGRAPHER: We are going off the
 20 record at 3:30 PM.
 21 [A brief recess was taken.]
 22 THE VIDEOGRAPHER: We are back on the
 23 record at 3:38 PM.
 24 BY MR. KO:

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1 Q. So the question that I had asked prior to
 2 taking that short break was whether or not there was a
 3 particular aspect of the SOM efforts that Buzzeo
 4 advised Mallinckrodt on, and I believe you said the
 5 answer was yes, and then I had asked you what aspects,
 6 and so I'll repeat that question now.
 7 What aspects was Buzzeo retained to advise
 8 Mallinckrodt on regarding Mallinckrodt's SOM efforts?
 9 MR. O'CONNOR: And I'm going to object on
 10 scope and attorney-client privilege with respect to the
 11 2018 engagement through outside counsel, but you can
 12 answer with respect to other engagements.
 13 A. So on the other engagements -- those were
 14 not SOM engagements.
 15 BY MR. KO:
 16 Q. So to be clear, in 2012, when you were
 17 saying earlier that Mallinckrodt had retained Buzzeo,
 18 that was not in connection with any SOM efforts?
 19 A. That's correct. I misspoke if that's what
 20 I had said.
 21 Q. And in 2012 then what -- for what purpose
 22 was Buzzeo retained by Mallinckrodt for?
 23 MR. O'CONNOR: Object to scope, but you
 24 can answer.

<p style="text-align: right;">Page 234</p> <p>1 A. There were recordkeeping discussions that</p> <p>2 they were providing us advice on and reviewing</p> <p>3 security.</p> <p>4 BY MR. KO:</p> <p>5 Q. Recordkeeping discussions regarding what</p> <p>6 records?</p> <p>7 A. Records that we needed to maintain,</p> <p>8 biannual inventories, records that the DEA may ask for</p> <p>9 if they come and do an inspection.</p> <p>10 Q. I see. And by security, what do you mean?</p> <p>11 A. The security practices at our Hobart</p> <p>12 facility.</p> <p>13 Q. Understood. And how long was their</p> <p>14 retention during that 2012 time period?</p> <p>15 MR. O'CONNOR: Object to scope.</p> <p>16 A. My recollection is several months.</p> <p>17 BY MR. KO:</p> <p>18 Q. So other than -- so now that I</p> <p>19 understand -- and thank you for the clarification</p> <p>20 regarding their role in 2012.</p> <p>21 So other than Frank Sapienza and Howard</p> <p>22 Davis and potentially this other entity that you don't</p> <p>23 recall, were there any other individuals or entities</p> <p>24 that Mallinckrodt retained for purposes of assisting</p>	<p style="text-align: right;">Page 236</p> <p>1 managers, Mallinckrodt also employs customer service</p> <p>2 representatives; correct?</p> <p>3 A. Correct.</p> <p>4 MR. O'CONNOR: Same objections.</p> <p>5 BY MR. KO:</p> <p>6 Q. And generally speaking, what's your</p> <p>7 understanding of what customer service</p> <p>8 representatives -- what function they perform?</p> <p>9 MR. O'CONNOR: Object to scope.</p> <p>10 A. So the customer service reps review every</p> <p>11 order that comes in and make sure that all the</p> <p>12 information is there, and --</p> <p>13 BY MR. KO:</p> <p>14 Q. And when you say every order, I just want</p> <p>15 to make sure I understand what you're saying when you</p> <p>16 mean every order. Is this every order ever between</p> <p>17 Mallinckrodt and any customer, or are you talking about</p> <p>18 every peculiar order or unusual order? What do you</p> <p>19 mean by every order?</p> <p>20 A. So --</p> <p>21 MR. O'CONNOR: Object to form.</p> <p>22 A. So the customer service reps review every</p> <p>23 order. I might not have been clear earlier. Customer</p> <p>24 service reps review every order. The customer service</p>
<p style="text-align: right;">Page 235</p> <p>1 Mallinckrodt with its SOM obligations?</p> <p>2 A. No, not that I can recall.</p> <p>3 Q. Okay. Thank you. Now, you're familiar</p> <p>4 with -- well, you are familiar with the compensation</p> <p>5 structure of certain customer service reps and national</p> <p>6 account managers at Mallinckrodt; correct?</p> <p>7 MR. O'CONNOR: Object to form and scope.</p> <p>8 A. I don't recall their compensation</p> <p>9 packages.</p> <p>10 BY MR. KO:</p> <p>11 Q. Are you familiar with the term NAMs or</p> <p>12 national account managers?</p> <p>13 A. Yes.</p> <p>14 Q. Mallinckrodt employs certain national</p> <p>15 account managers; correct?</p> <p>16 A. Correct.</p> <p>17 Q. And they have responsibility with respect</p> <p>18 to Mallinckrodt customers, including wholesale</p> <p>19 distributors; correct?</p> <p>20 MR. O'CONNOR: Objection to scope and</p> <p>21 form.</p> <p>22 A. Yes.</p> <p>23 BY MR. KO:</p> <p>24 Q. And in addition to national account</p>	<p style="text-align: right;">Page 237</p> <p>1 managers review those peculiar orders.</p> <p>2 BY MR. KO:</p> <p>3 Q. I see. And --</p> <p>4 A. So I apologize if I misspoke earlier</p> <p>5 today. I might have used those terms synonymously when</p> <p>6 you were asking me a certain question. But the reps</p> <p>7 review every order and the managers review the peculiar</p> <p>8 orders.</p> <p>9 Q. Okay. Thank you for that clarification.</p> <p>10 And by every order, just so I understand clearly, you</p> <p>11 are referring to every order between Mallinckrodt and</p> <p>12 one of its customers, the wholesale distributor;</p> <p>13 correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And with respect to national account</p> <p>16 managers, their compensation is tied to the amount of</p> <p>17 Mallinckrodt prescription opioids they sell to</p> <p>18 customers; is that accurate?</p> <p>19 MR. O'CONNOR: Objection to scope and</p> <p>20 form.</p> <p>21 A. I'm sorry. I don't know that.</p> <p>22 BY MR. KO:</p> <p>23 Q. You have no understanding of how national</p> <p>24 account managers are compensated?</p>

<p style="text-align: right;">Page 238</p> <p>1 A. No, I do not.</p> <p>2 MR. O'CONNOR: Same --</p> <p>3 BY MR. KO:</p> <p>4 Q. Do you have any understanding of how</p> <p>5 customer service representatives are compensated?</p> <p>6 MR. O'CONNOR: Same objection.</p> <p>7 A. I do not.</p> <p>8 MR. KO: And I'll just note for the record</p> <p>9 to preserve it that I believe Mr. Gillies was supposed</p> <p>10 to be prepared to testify regarding any compensation to</p> <p>11 any person or committee with any responsibility for any</p> <p>12 of the level of sales of controlled substances or</p> <p>13 opioid products, and so I believe we were expecting</p> <p>14 testimony related to your understanding of that topic,</p> <p>15 and I'll note for the record that it appears that Mr.</p> <p>16 Gillies is unprepared to testify on that topic.</p> <p>17 BY MR. KO:</p> <p>18 Q. In addition to national account managers</p> <p>19 and customer service representatives, do you know any</p> <p>20 other categories of employees at Mallinckrodt who were</p> <p>21 involved in the marketing and sales of Mallinckrodt's</p> <p>22 prescription opioids?</p> <p>23 A. I do not.</p> <p>24 Q. Now, earlier today we had talked about the</p>	<p style="text-align: right;">Page 240</p> <p>1 Q. In addition to Heather White, do you</p> <p>2 recall anyone else at DEA you discussed DEA's</p> <p>3 investigation with?</p> <p>4 A. I believe Susan Baker was part of that</p> <p>5 team.</p> <p>6 Q. Was she also in the DEA Albany office?</p> <p>7 A. She was out of the DEA New York office.</p> <p>8 Q. Other than Ms. Baker or Ms. White, do you</p> <p>9 recall discussing DEA's investigation of Mallinckrodt</p> <p>10 that led to the memorandum of understanding with any</p> <p>11 other DEA individual?</p> <p>12 A. No, and this -- sorry. Maybe I</p> <p>13 misunderstood your question. This would have been pre</p> <p>14 any negotiations on that agreement. So there were</p> <p>15 discussions about the investigation, but pre the</p> <p>16 negotiations, just to make it clear.</p> <p>17 Q. I understand.</p> <p>18 A. Okay?</p> <p>19 Q. Okay. So the record is clear then, and</p> <p>20 the way I understand your testimony, is that you spoke</p> <p>21 with Ms. White and Ms. Baker regarding the DEA's</p> <p>22 investigation of Mallinckrodt at some point after 2011</p> <p>23 but before --</p> <p>24 A. So --</p>
<p style="text-align: right;">Page 239</p> <p>1 memorandum of understanding entered into between</p> <p>2 Mallinckrodt and the DEA in 2017. Do you recall that?</p> <p>3 A. Yes.</p> <p>4 Q. Were you involved at all in the</p> <p>5 negotiations leading up to that memorandum of</p> <p>6 understanding?</p> <p>7 A. No.</p> <p>8 Q. Do you have any understanding of when</p> <p>9 Mallinckrodt first became aware that it was being</p> <p>10 formally investigated by the DEA?</p> <p>11 A. September of 2011.</p> <p>12 Q. And was that pursuant to a subpoena that</p> <p>13 Mallinckrodt received?</p> <p>14 A. I don't know that.</p> <p>15 Q. And a moment ago you said you weren't</p> <p>16 involved at all in the negotiations leading up to the</p> <p>17 memorandum of understanding. But were you -- did you</p> <p>18 have any discussions with DEA regarding their</p> <p>19 investigation that led to that memorandum of</p> <p>20 understanding?</p> <p>21 A. Yes.</p> <p>22 Q. And who did you have those discussions</p> <p>23 with?</p> <p>24 A. Heather White, DEA Albany.</p>	<p style="text-align: right;">Page 241</p> <p>1 Q. -- Mallinckrodt and DEA negotiated the</p> <p>2 memorandum of understanding? Is that accurate?</p> <p>3 A. To be more clear, at some time after June</p> <p>4 of 2012.</p> <p>5 Q. Okay. And when did the negotiations that</p> <p>6 led up to the memorandum of understanding begin between</p> <p>7 Mallinckrodt and DEA?</p> <p>8 A. My recollection is that they were ongoing</p> <p>9 for I think more than a year.</p> <p>10 Q. So at some -- safe to say that the</p> <p>11 negotiations regarding the memorandum of understanding</p> <p>12 began at some time in 2016?</p> <p>13 A. I believe that's accurate.</p> <p>14 Q. And so your discussions with Ms. White and</p> <p>15 Ms. Baker regarding DEA's investigation occurred at</p> <p>16 some point between June of 2012 and before 2016?</p> <p>17 A. Correct.</p> <p>18 Q. And in connection with the investigation,</p> <p>19 do you know whether -- well, strike that.</p> <p>20 In your discussions with Ms. White and Ms.</p> <p>21 Baker, were you ever formally interviewed or did you</p> <p>22 ever sit for any kind of formal interview with the DEA?</p> <p>23 A. No.</p> <p>24 Q. Are you aware of whether or not</p>

<p style="text-align: right;">Page 242</p> <p>1 Mallinckrodt had any interviews with any Mallinckrodt 2 employee arising out of its investigation of 3 Mallinckrodt?</p> <p>4 A. So I'm sorry. Could you repeat that 5 question?</p> <p>6 Q. Sure. Are you aware of whether 7 Mallinckrodt sat for any interviews -- or strike that. 8 Are you aware of whether or not the DEA 9 had any interviews with any Mallinckrodt employee 10 arising out of the DEA's investigation of Mallinckrodt?</p> <p>11 A. No.</p> <p>12 Q. And do you have knowledge of whether or 13 not that is in fact the case, or are you saying you 14 don't recall whether or not that occurred?</p> <p>15 A. I have no recollection that anybody was 16 interviewed.</p> <p>17 Q. Do you know if any Mallinckrodt employee 18 provided any statements -- sworn statements to the DEA 19 regarding Mallinckrodt's investigation?</p> <p>20 A. No.</p> <p>21 Q. Or excuse me. Regarding the DEA's 22 investigation of Mallinckrodt?</p> <p>23 A. No.</p> <p>24 Q. And do you know -- so in addition to your</p>	<p style="text-align: right;">Page 244</p> <p>1 A. The meeting with the DEA where Susan Baker 2 and Heather White were present discussing their 3 investigation.</p> <p>4 Q. I see. And you were present at that 5 meeting as well?</p> <p>6 A. I was.</p> <p>7 Q. So in addition to Mr. Weustner, Mr. 8 Lohman, and yourself, were there any other Mallinckrodt 9 employees that were present at the meeting?</p> <p>10 A. Not that I can recall.</p> <p>11 Q. And from the DEA's side, other than Ms. 12 Baker and Ms. White, were there any other DEA officials 13 there?</p> <p>14 A. There were.</p> <p>15 Q. And who were they?</p> <p>16 A. One was their special agent in charge of 17 their New York office. And I'm sorry, I do not recall 18 his name. I believe there was a DEA representative 19 from Washington D.C. I'm sorry, I do not remember his 20 name. And I can't recall if there was any other DEA 21 personnel there.</p> <p>22 Q. And when did this meeting take place?</p> <p>23 A. I don't recall. I'm going to say spring 24 2014.</p>
<p style="text-align: right;">Page 243</p> <p>1 communications with Ms. White and Ms. Baker, do you 2 know whether or not any other Mallinckrodt employees 3 communicated with DEA regarding its investigation of 4 Mallinckrodt?</p> <p>5 A. Yes.</p> <p>6 Q. And which individuals would those be?</p> <p>7 A. Joe Weustner and I believe Don Lohman.</p> <p>8 Q. And you said Joe --</p> <p>9 A. Weustner.</p> <p>10 Q. Joe Weustner?</p> <p>11 A. W-E-U-S-T-N-E-R.</p> <p>12 Q. And what is his job title at Mallinckrodt?</p> <p>13 A. He was a VP associate general counsel.</p> <p>14 Q. In addition to Joe and Don, do you recall 15 any other individuals who communicated with the DEA 16 regarding their investigation?</p> <p>17 A. No.</p> <p>18 Q. Do you recall whether or not Ms. Harper 19 communicated with the DEA regarding their investigation 20 of Mallinckrodt?</p> <p>21 A. I can't recall whether she was at the 22 meeting.</p> <p>23 Q. And you just referenced a meeting. What 24 meeting are you describing?</p>	<p style="text-align: right;">Page 245</p> <p>1 Q. Okay. Thank you. That's helpful. 2 Following the -- this meeting, do you recall any other 3 meetings in which you were present with the DEA 4 regarding its investigation of Mallinckrodt?</p> <p>5 A. No.</p> <p>6 Q. And in addition to this meeting, do you 7 recall any other meetings, regardless of whether or not 8 you were involved with the DEA, regarding its 9 investigation of Mallinckrodt?</p> <p>10 A. I do not.</p> <p>11 Q. You don't recall, or you don't believe any 12 such meetings took place?</p> <p>13 A. I don't recall.</p> <p>14 Q. Now, the agreement resulted among other 15 things in a \$35 million payment made by Mallinckrodt to 16 the Department of Justice; correct?</p> <p>17 A. Yes.</p> <p>18 Q. Were you involved -- or who was involved 19 in the negotiation of the monetary fine?</p> <p>20 MR. O'CONNOR: Objection to form.</p> <p>21 A. There was legal counsel involved.</p> <p>22 BY MR. KO:</p> <p>23 Q. So is it your understanding that it was 24 primarily handled by Mr. Lohman and Mr. Weustner?</p>

<p style="text-align: right;">Page 246</p> <p>1 A. Yes.</p> <p>2 Q. Was there anyone outside of the legal</p> <p>3 department or legal counsel that handled the</p> <p>4 negotiations over the monetary fine that Mallinckrodt</p> <p>5 paid to the DEA?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. Within Mallinckrodt?</p> <p>8 BY MR. KO:</p> <p>9 Q. Yes.</p> <p>10 A. No.</p> <p>11 Q. So you don't believe anyone outside of</p> <p>12 legal counsel handled --</p> <p>13 A. I don't recall anyone else outside legal</p> <p>14 counsel.</p> <p>15 Q. -- being involved in the discussions</p> <p>16 about the monetary fine imposed on Mallinckrodt;</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. Now, in addition to DEA's investigation</p> <p>20 which resulted in the 2017 memorandum of understanding</p> <p>21 and the \$35 million fine, there have been other</p> <p>22 investigations by other government entities into</p> <p>23 Mallinckrodt; is that fair to say?</p> <p>24 MR. O'CONNOR: Objection to form.</p>	<p style="text-align: right;">Page 248</p> <p>1 investigations performed by any entity regarding</p> <p>2 Mallinckrodt's manufacturing or distribution of its</p> <p>3 opioid products?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. I don't know of any.</p> <p>6 BY MR. KO:</p> <p>7 Q. Were you -- was it the case that earlier</p> <p>8 last year in the beginning of 2018, prosecutors from</p> <p>9 the Southern District of Florida had issued grand jury</p> <p>10 subpoenas to Mallinckrodt regarding its manufacturing</p> <p>11 and distribution of prescription opioids?</p> <p>12 A. I'm not aware of that.</p> <p>13 Q. You're not aware of that? Are you aware</p> <p>14 of any other subpoenas issued by the Department of</p> <p>15 Justice at any time regarding Mallinckrodt's marketing</p> <p>16 or manufacturing of any of its generic or branded</p> <p>17 opioid products?</p> <p>18 A. I am not.</p> <p>19 Q. So are you aware of any 2017 subpoena by</p> <p>20 the Department of Justice regarding Mallinckrodt's</p> <p>21 manufacturing and marketing of Exalgo, Xartemis, and</p> <p>22 Roxicodone, among other products?</p> <p>23 A. I am not.</p> <p>24 Q. Are you aware of any civil investigative</p>
<p style="text-align: right;">Page 247</p> <p>1 A. What government entities?</p> <p>2 BY MR. KO:</p> <p>3 Q. Sure. Fair enough. Are you aware of any</p> <p>4 other investigations done by any senators with respect</p> <p>5 to Mallinckrodt's marketing or distribution of its</p> <p>6 opioid products?</p> <p>7 MR. O'CONNOR: Object to form.</p> <p>8 A. I'm aware of a senator requesting</p> <p>9 information.</p> <p>10 BY MR. KO:</p> <p>11 Q. And which senator was that?</p> <p>12 A. Claire McCaskill.</p> <p>13 Q. And when was that?</p> <p>14 A. I don't recall what the time frame was.</p> <p>15 Q. And who was involved in preparing the</p> <p>16 information in response to Senator McCaskill's request?</p> <p>17 A. My understanding, legal counsel.</p> <p>18 Q. And do you have any understanding of what</p> <p>19 information Senator McCaskill requested of</p> <p>20 Mallinckrodt?</p> <p>21 A. I do not.</p> <p>22 Q. In addition to Senator McCaskill's request</p> <p>23 and the DEA's investigation which resulted in the 2017</p> <p>24 memorandum of understanding, are you aware of any other</p>	<p style="text-align: right;">Page 249</p> <p>1 demands from any other officials -- from any officials</p> <p>2 in any state in the United States regarding</p> <p>3 Mallinckrodt's marketing and distribution of</p> <p>4 prescription opioids?</p> <p>5 A. State authorities? I'm not aware of any.</p> <p>6 Q. Are you aware of any civil investigative</p> <p>7 demand by the State of Washington regarding</p> <p>8 Mallinckrodt manufacture and distribution of its</p> <p>9 prescription opioids?</p> <p>10 A. I am not.</p> <p>11 Q. Are you aware of Missouri's civil</p> <p>12 investigative demand of information related to</p> <p>13 Mallinckrodt's manufacture and distribution of its</p> <p>14 prescription opioids?</p> <p>15 A. I am not.</p> <p>16 Q. Now, one of the -- as we discussed earlier</p> <p>17 today, one of the primary responsibilities of the DEA</p> <p>18 compliance group is to communicate with the DEA</p> <p>19 regarding Mallinckrodt's annual quota request. Is that</p> <p>20 accurate?</p> <p>21 A. Yes.</p> <p>22 Q. And there are different types of quotas</p> <p>23 set by the DEA; correct?</p> <p>24 A. Correct.</p>

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<p>1 Q. And can you describe to the court what</p> <p>2 those different types of quotas consist of?</p> <p>3 A. For the individual controlled substance</p> <p>4 products, the DEA has a set quota that they then give</p> <p>5 to the manufacturers.</p> <p>6 Q. And is that a reference to a manufacturing</p> <p>7 quota?</p> <p>8 A. Yes.</p> <p>9 Q. And in addition to the manufacturing</p> <p>10 quota, there's also -- the DEA has -- provides guidance</p> <p>11 on procurement quota as well; correct?</p> <p>12 A. Correct.</p> <p>13 Q. And what does procurement quota consist</p> <p>14 of?</p> <p>15 A. So the manufacturing quota would be for</p> <p>16 our St. Louis facility, and the procurement quota would</p> <p>17 be for our Hobart facility on the number of tablets</p> <p>18 that we're going to make.</p> <p>19 Q. So in other words, would it be fair to say</p> <p>20 that the procurement quota governs the amount that</p> <p>21 Mallinckrodt can turn into an actual extended unit</p> <p>22 release or pill -- strike that. Let me ask it a</p> <p>23 different way.</p> <p>24 The manufacturing quota established by the</p>	<p>1 process?</p> <p>2 A. I am not.</p> <p>3 Q. Who on the DEA compliance team is</p> <p>4 responsible for working with the DEA and Mallinckrodt's</p> <p>5 annual quota request today?</p> <p>6 A. Karen Harper.</p> <p>7 Q. And in addition to Karen Harper, are there</p> <p>8 any other individuals that assist her in the annual</p> <p>9 quota request?</p> <p>10 A. It's my recollection that Dave Hunter</p> <p>11 assists her on the manufacturing for the St. Louis</p> <p>12 plant, and Eileen Spaulding, it's my understanding,</p> <p>13 assists her on the procurement.</p> <p>14 Q. And is it your understanding that Ms.</p> <p>15 Harper had the primary responsibility of working with</p> <p>16 the DEA regarding Mallinckrodt's annual quota</p> <p>17 request -- or strike that.</p> <p>18 How long has Ms. Harper had the</p> <p>19 responsibility of working with the DEA regarding</p> <p>20 Mallinckrodt's quota requests?</p> <p>21 A. I know that it predates 2008.</p> <p>22 Q. And throughout that time period, there was</p> <p>23 no other individual who had that primary responsibility</p> <p>24 at Mallinckrodt; is that accurate?</p>
Page 251	Page 253
<p>1 DEA governs how much raw product Mallinckrodt can</p> <p>2 manufacture; correct?</p> <p>3 A. Correct.</p> <p>4 Q. And the procurement quota governs how much</p> <p>5 of that raw product Mallinckrodt can turn into a pill;</p> <p>6 correct?</p> <p>7 A. Yes, and in our request to the DEA, we</p> <p>8 tell them how many pills it's estimated that we would</p> <p>9 make.</p> <p>10 Q. And so in connection with your</p> <p>11 communications with the DEA, are you saying that there</p> <p>12 is a separate procedure with respect to the procurement</p> <p>13 quota relative to the manufacturing quota, or would you</p> <p>14 regularly communicate with the DEA regarding both</p> <p>15 quotas?</p> <p>16 A. Yeah.</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. Both quotas.</p> <p>19 BY MR. KO:</p> <p>20 Q. And regarding the manufacturing quota set</p> <p>21 by the DEA, they generally set that once a year;</p> <p>22 correct?</p> <p>23 A. That's my understanding.</p> <p>24 Q. And are you currently involved in that</p>	<p>1 A. Yes.</p> <p>2 Q. Now, we've made mention to -- we've made</p> <p>3 mention to Mallinckrodt's St. Louis and Hobart</p> <p>4 facilities. Is the St. Louis facility synonymous or</p> <p>5 different from the Webster Groves facility?</p> <p>6 A. It's different.</p> <p>7 Q. And what did the -- can you describe to</p> <p>8 the court what the Webster Groves facility was in</p> <p>9 charge of or what happened at the Webster Groves</p> <p>10 facility?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. Our Webster Groves facility is an R & D</p> <p>13 facility.</p> <p>14 BY MR. KO:</p> <p>15 Q. Got it. Was there any manufacturing of</p> <p>16 opioids done at the Webster Groves facility?</p> <p>17 A. Time frame?</p> <p>18 Q. At any time.</p> <p>19 A. Yes.</p> <p>20 Q. And when was that?</p> <p>21 A. November 2018.</p> <p>22 Q. So somewhat recently?</p> <p>23 A. Uh-huh.</p> <p>24 Q. Prior to November of 2018, was there any</p>

<p style="text-align: right;">Page 254</p> <p>1 manufacturing that occurred at the Webster Groves 2 facility?</p> <p>3 A. I'm unaware of any manufacturing taking 4 place.</p> <p>5 Q. And prior to 2018, the Webster Groves 6 facility was primarily utilized as an R & D facility; 7 is that accurate?</p> <p>8 A. Was and is. Yeah.</p> <p>9 Q. I'm going to hand you a copy of what's 10 been marked as Gillies Exhibit 26. 11 [Exhibit Mallinckrodt-Gillies-026 12 marked for identification.]</p> <p>13 Q. And for the record, this ends in Bates 14 3044340, and it's an e-mail chain from June 20th, 2012, 15 between Kenneth Yamashita and Eileen Spaulding. 16 And I just have a quick question on this 17 e-mail. Feel free to review it if you need to in 18 responding to my question.</p> <p>19 A. Uh-huh.</p> <p>20 Q. But at the top, Ken indicates, quote, did 21 you get the impression now that if our quota 22 justification and suspicious order monitoring program 23 is good, we will get the quota or at least some 24 portion, end quote.</p>	<p style="text-align: right;">Page 256</p> <p>1 A. And then let me answer that. Okay. So 2 could you repeat your question now?</p> <p>3 Q. Sure. Do you have any recollection of 4 whether or not the quota -- whether or not the SOM 5 program that Mallinckrodt implemented was tied in any 6 way to Mallinckrodt's quota requests?</p> <p>7 MR. O'CONNOR: Object to form.</p> <p>8 A. No.</p> <p>9 BY MR. KO:</p> <p>10 Q. Did Mallinckrodt ever learn from the DEA 11 if -- that if it had a robust SOM program it would more 12 likely be able to maximize its quota requests?</p> <p>13 A. No.</p> <p>14 Q. Did you ever -- did you review any 15 documents in preparation for this deposition today that 16 had any connection between quota requests and 17 Mallinckrodt's SOM program?</p> <p>18 A. Not that I recall.</p> <p>19 Q. You can set that one aside. So earlier we 20 had talked about the meeting that Mallinckrodt had with 21 DEA in August of 2011. Do you recall that?</p> <p>22 A. Yes.</p> <p>23 Q. And do you recall who requested that 24 meeting?</p>
<p style="text-align: right;">Page 255</p> <p>1 Did I read that correctly?</p> <p>2 A. Yes.</p> <p>3 Q. First of all, do you know who Ken 4 Yamashita is?</p> <p>5 A. Yes.</p> <p>6 Q. And who is he?</p> <p>7 A. He was the head of our Hobart facility.</p> <p>8 Q. And what do you -- and by head of Hobart 9 facility, what exactly do you mean?</p> <p>10 A. He was -- he ran the administration of the 11 facility.</p> <p>12 Q. And he's asking a question to Eileen of 13 whether or not the quota justification -- or strike 14 that.</p> <p>15 He's asking whether or not the SO -- if 16 the SOM program is adequate that Mallinckrodt would 17 obtain the quota that they sought.</p> <p>18 Do you have any recollection of whether or 19 not the quota justification or the quota request was 20 ever tied to Mallinckrodt's SOM program?</p> <p>21 MR. O'CONNOR: Objection to form.</p> <p>22 A. Can I just read the rest of this document? 23 BY MR. KO:</p> <p>24 Q. Sure.</p>	<p style="text-align: right;">Page 257</p> <p>1 A. I know that we had requested a meeting 2 with the DEA since the spring of 2011, and I think this 3 August meeting was in response to our ongoing request 4 to meet with them.</p> <p>5 Q. And is it fair to say that during this 6 meeting, two of the issues that were discussed were 7 Mallinckrodt's SOM program and issues with respect to 8 Mallinckrodt's quota requests?</p> <p>9 MR. O'CONNOR: Objection to form.</p> <p>10 A. I know one of the issues was we wanted to 11 tell DEA about our SOM program and everything that we 12 were doing.</p> <p>13 BY MR. KO:</p> <p>14 Q. Okay. And was another topic of the 15 meeting issues with respect to Mallinckrodt's quota 16 requests?</p> <p>17 A. I don't recall that.</p> <p>18 Q. I'm going to hand you a copy of what's 19 going to be marked as Gillies Exhibit 27. 20 [Exhibit Mallinckrodt-Gillies-027 21 marked for identification.]</p> <p>22 Q. Does this document look familiar at all to 23 you?</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 258</p> <p>1 Q. And did you review this document in 2 preparation for this deposition today?</p> <p>3 A. No.</p> <p>4 Q. And how does this document look familiar 5 to you? Did you review it at some point separate and 6 apart from preparing for this deposition?</p> <p>7 A. Yes.</p> <p>8 Q. And approximately when do you think that 9 was?</p> <p>10 A. I believe this is one of the documents I 11 reviewed after I joined Mallinckrodt.</p> <p>12 Q. And as I understand it, I believe this is 13 a deck that Mallinckrodt used during that meeting and 14 presented it to the DEA.</p> <p>15 Is that consistent with your 16 understanding?</p> <p>17 A. Yes.</p> <p>18 Q. And I just have a few quick questions 19 about it. On the second page of this deck there is a 20 reference made to suspicious order monitoring 21 presentation agenda. Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. So just so the record is clear, the 24 primary topic of the DEA meeting in August of 2011 was</p>	<p style="text-align: right;">Page 260</p> <p>1 discussed during this meeting.</p> <p>2 A. Uh-huh.</p> <p>3 Q. But does this refresh your recollection at 4 all as to what aspects of quota were discussed with the 5 DEA during this meeting?</p> <p>6 A. No.</p> <p>7 Q. No reason to dispute that quota issues 8 were discussed with the DEA during August 23rd, 2011, 9 though; right?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. So it's a bullet point on this slide. I 12 don't know whether they actually talked about it. I 13 have no recollection of that.</p> <p>14 BY MR. KO:</p> <p>15 Q. Fair enough. You can set that aside. I'm 16 going to hand you a copy of what's marked as Gillies 17 Exhibit 28.</p> <p>18 [Exhibit Mallinckrodt-Gillies-028 19 marked for identification.]</p> <p>20 Q. And for the record, this document is 21 titled draft notes for SOM steering committee meeting, 22 9-28-11, and it ends in Bates 2077756.</p> <p>23 And Mr. Gillies, this appears to be -- 24 well, earlier we had went over certain policies</p>
<p style="text-align: right;">Page 259</p> <p>1 regarding Mallinckrodt's SOM program; correct?</p> <p>2 A. Correct.</p> <p>3 MR. O'CONNOR: Objection to form.</p> <p>4 BY MR. KO:</p> <p>5 Q. And if you look at Page 7 of this report, 6 there's an additional reference made to subpoenas, SOM 7 quota review, and business relationships. Do you see 8 that?</p> <p>9 A. Yes.</p> <p>10 Q. And the context of these references is 11 being made in the context of the SOM program challenges 12 and issues. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. So would it be accurate to say that in 15 addition to Mallinckrodt SOM being reviewed at the 16 meeting, Mallinckrodt also discussed challenges and 17 issues with respect to subpoenas it was receiving, SOM 18 quota review, and certain business relationships it 19 had?</p> <p>20 MR. O'CONNOR: Objection to form.</p> <p>21 A. That's what this slide says.</p> <p>22 BY MR. KO:</p> <p>23 Q. And do you -- I know a moment ago that you 24 said you weren't familiar with whether or not quota was</p>	<p style="text-align: right;">Page 261</p> <p>1 regarding Mallinckrodt's SOM, and in some of those 2 policies there was reference made to a steering 3 committee; correct?</p> <p>4 A. Yes.</p> <p>5 Q. And from time to time members of the 6 steering committee would meet to discuss Mallinckrodt's 7 SOM program; correct?</p> <p>8 A. Correct.</p> <p>9 Q. And this appears to be notes that are 10 being prepared in connection with the steering 11 committee meeting; right?</p> <p>12 A. Correct.</p> <p>13 Q. And so halfway down the first page there 14 is a brief recap of the DEA meeting. You see that?</p> <p>15 A. Yes.</p> <p>16 Q. And it appears that their recap is 17 being -- that Don is providing the recap, and I imagine 18 that would be Don Lohman?</p> <p>19 A. That would be my understanding.</p> <p>20 Q. And there are a variety of things that are 21 discussed here, but it appears that the summary of the 22 meeting, Don indicates that, quote, at our request, on 23 August 23rd, 2011, met with the DEA office of diversion 24 control and quota section in Washington D.C. to discuss</p>

<p style="text-align: right;">Page 262</p> <p>1 our SOM program, which monitors suspicious orders of</p> <p>2 controlled substances and our outstanding quota</p> <p>3 requests, end quote.</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. So is it accurate to say that -- and just</p> <p>7 so the record is clear -- that during the August 2011</p> <p>8 meeting, two of the topics that were discussed were</p> <p>9 suspicious order monitoring and outstanding quota</p> <p>10 requests of Mallinckrodt?</p> <p>11 A. Yes.</p> <p>12 Q. That's all I have with that document. I'm</p> <p>13 going to hand you a copy of what's been marked as</p> <p>14 Gillies Exhibit 29.</p> <p>15 [Exhibit Mallinckrodt-Gillies-029</p> <p>16 marked for identification.]</p> <p>17 Q. And for the record, this document ends in</p> <p>18 Bates 284620 and is an e-mail from Karen Harper to</p> <p>19 herself dated Saturday, April 23rd, 2011. And it</p> <p>20 appears to be some notes that she took from a DEA</p> <p>21 conference that she attended.</p> <p>22 Did you -- does this document look</p> <p>23 familiar at all to you?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 264</p> <p>1 of whether or not Mallinckrodt employees attended DEA</p> <p>2 conferences, and I believe you said yes, and my</p> <p>3 follow-up question was whether or not you had an</p> <p>4 understanding of how frequent they attended such</p> <p>5 conferences.</p> <p>6 A. Okay. So I think I did misunderstand the</p> <p>7 way you phrased it, but that time the answer is yes,</p> <p>8 and I believe it was annually.</p> <p>9 Q. And was it typically the case that Ms.</p> <p>10 Harper would attend?</p> <p>11 A. Yes.</p> <p>12 Q. And do you know any other Mallinckrodt</p> <p>13 employees that attended any annual DEA conferences?</p> <p>14 A. Eileen Spaulding. Time frame?</p> <p>15 Q. At any time.</p> <p>16 A. Jen Buist. I can't recall if there was</p> <p>17 anybody else.</p> <p>18 Q. At the bottom of this e-mail, Karen Harper</p> <p>19 indicates that, quote, someone in your company is</p> <p>20 accountable for making decisions about customers, SOM.</p> <p>21 All decisions should be documented in file by customer.</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. So is it accurate to say that Karen Harper</p>
<p style="text-align: right;">Page 263</p> <p>1 Q. Did you review this document in connection</p> <p>2 with your preparing for this deposition today?</p> <p>3 A. No.</p> <p>4 Q. Do you know who Michael Morley is?</p> <p>5 A. I do not.</p> <p>6 Q. Do you know who Kyle Wright is?</p> <p>7 A. I do not.</p> <p>8 Q. Do you have any understanding of how</p> <p>9 frequent members of the DEA compliance team attended</p> <p>10 DEA conferences regarding Mallinckrodt's CSA</p> <p>11 obligations?</p> <p>12 A. I do not.</p> <p>13 Q. Do you know whether or not Mallinckrodt</p> <p>14 employees ever attended DEA conferences regarding their</p> <p>15 CSA obligations?</p> <p>16 A. Yes.</p> <p>17 Q. And do you have any understanding of how</p> <p>18 frequent they attended such conferences?</p> <p>19 A. So can you restate that question? Because</p> <p>20 I may have misunderstood the previous question.</p> <p>21 Q. Well, I had asked you whether or not --</p> <p>22 sure.</p> <p>23 A. Okay.</p> <p>24 Q. I asked you whether or not you were aware</p>	<p style="text-align: right;">Page 265</p> <p>1 is indicating that there should be some sort of</p> <p>2 documentation procedure with respect to all decisions</p> <p>3 regarding SOM?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. So can you repeat that question?</p> <p>6 BY MR. KO:</p> <p>7 Q. Sure. Is it accurate to say that Karen</p> <p>8 Harper is indicating that there should be some sort of</p> <p>9 documentation procedure with respect to all decisions</p> <p>10 regarding SOM?</p> <p>11 A. Yes.</p> <p>12 Q. And we had talked about it a little bit</p> <p>13 before, but are you aware of whether or not there was</p> <p>14 any kind of formal documentation procedure regarding</p> <p>15 Mallinckrodt's SOM in the 2011 time period?</p> <p>16 MR. O'CONNOR: Objection to form.</p> <p>17 A. I believe there was.</p> <p>18 BY MR. KO:</p> <p>19 Q. And what is that understanding based upon?</p> <p>20 A. From reviewing procedures.</p> <p>21 Q. And which -- the same procedures we were</p> <p>22 kind of discussing before?</p> <p>23 A. Yes.</p> <p>24 Q. Outside of those procedures, did you</p>

<p style="text-align: right;">Page 266</p> <p>1 review any other documents that suggested there was a 2 formal documentation procedure governing the decisions 3 made by any individuals at Mallinckrodt with respect to 4 its SOM?</p> <p>5 A. I don't recall that.</p> <p>6 Q. So is it fair to say that at least as of 7 the date of this letter, Mallinckrodt is aware that DEA 8 is expecting some sort of formal documentation 9 regarding its SOM decisions and policies?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. That's what this note references.</p> <p>12 BY MR. KO:</p> <p>13 Q. So is it -- I understand that that's what 14 the note references, but I'm asking you as a 15 designee -- a corporate designee of Mallinckrodt 16 sitting here today, yes or no, is it fair to say that 17 as of the date of this letter, Mallinckrodt is aware 18 that DEA is expecting some sort of formal documentation 19 procedure regarding its SOM decisions and policies?</p> <p>20 MR. O'CONNOR: Objection to form.</p> <p>21 A. Yes.</p> <p>22 BY MR. KO:</p> <p>23 Q. And underneath the section Kyle Wright, 24 there's an indication, quote, I am coming. You don't</p>	<p style="text-align: right;">Page 268</p> <p>1 Q. And we had established that chargeback 2 data allowed Mallinckrodt to see where its pills were 3 going and specifically to which pharmacies and clinics 4 Mallinckrodt drugs were going after Mallinckrodt 5 shipped to its distributors; correct?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. Not all pharmacies. There has to be a 8 chargeback relationship and corrected as retroactive.</p> <p>9 MR. O'CONNOR: Counsel, just a heads-up. 10 By our count, you have about a minute.</p> <p>11 MR. KO: Okay. I have one more -- I 12 thought I had about 15 minutes. But --</p> <p>13 MR. O'CONNOR: You're welcome to check. 14 How much --</p> <p>15 MR. KO: It's your math versus Alison's, 16 but --</p> <p>17 MR. O'CONNOR: How much time --</p> <p>18 MR. KO: Not to put you on the spot, but I 19 got one more document.</p> <p>20 MR. O'CONNOR: Okay.</p> <p>21 THE VIDEOGRAPHER: I've got five hours, 25 22 minutes.</p> <p>23 MR. KO: Okay.</p> <p>24 MR. O'CONNOR: And we had 5:25 for the</p>
<p style="text-align: right;">Page 267</p> <p>1 want me. I can tear you apart. If DEA can see where 2 drugs are going, Mallinckrodt knows full well where 3 drugs are going.</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. And so is it fair to say that the DEA 7 certainly expects Mallinckrodt to understand where all 8 of its drugs are going even after Mallinckrodt ships 9 them to its distributor customers?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. I don't know that that's what it's saying, 12 because our product goes to the distributors and 13 wholesalers. So I don't see a reference that it says 14 that this goes further beyond that.</p> <p>15 But in this case, the DEA can see, because 16 they've got all the information, right, through ARCOS. 17 So they see where it goes, so they can see that we're 18 sending it to the distributors or wholesalers, but 19 because they get the ARCOS information from others, 20 they can see where that goes too.</p> <p>21 BY MR. KO:</p> <p>22 Q. And we had discussed earlier the concept 23 of chargeback data; correct?</p> <p>24 A. Correct.</p>	<p style="text-align: right;">Page 269</p> <p>1 limit; right?</p> <p>2 MR. KO: All right.</p> <p>3 MR. O'CONNOR: But one document quickly.</p> <p>4 MR. KO: Okay. Thank you for that.</p> <p>5 BY MR. KO:</p> <p>6 Q. There's -- Mr. Gillies, I'm handing you a 7 copy of a document that's been marked as Gillies 8 Exhibit --</p> <p>9 MS. GAFFNEY: 30.</p> <p>10 BY MR. KO:</p> <p>11 Q. -- 30. Thank you.</p> <p>12 [Exhibit Mallinckrodt-Gillies-030 13 marked for identification.]</p> <p>14 Q. And for the record, this is a March 18th, 15 2013, correspondence dated -- or I said the date 16 already -- ending in Bates 8434954. And I have a very 17 specific question.</p> <p>18 A. Okay.</p> <p>19 Q. So again, if you need to read more of the 20 document, please feel free to do so.</p> <p>21 But first of all, this appears to be a 22 communication made by an outside counsel for 23 Mallinckrodt to an assistant U.S. attorney. Is that 24 accurate?</p>

<p style="text-align: right;">Page 270</p> <p>1 A. Yes.</p> <p>2 Q. And in Section 1 of the document, there is</p> <p>3 reference made to a certain percentage of oxy 15s and</p> <p>4 oxy 30s distributed by certain of Mallinckrodt's</p> <p>5 customers; right?</p> <p>6 A. Yes.</p> <p>7 Q. And those customers are the big three</p> <p>8 distributors and H.D. Smith; correct?</p> <p>9 A. Correct.</p> <p>10 Q. And they distributed oxy 15s and oxy 30s;</p> <p>11 correct?</p> <p>12 A. Correct.</p> <p>13 Q. And turning to the next page -- this is</p> <p>14 just the final line of questioning. Do you see the</p> <p>15 section Page 3 -- or sorry -- do you see the section</p> <p>16 Question 3?</p> <p>17 A. Just for my reference in the future, if I</p> <p>18 have to go back, could you put the Bates number on it?</p> <p>19 Because you said this was the only Bates number. You</p> <p>20 said ending in this number, but is this a new number</p> <p>21 here?</p> <p>22 Q. Right. That's just the next page --</p> <p>23 A. Okay.</p> <p>24 Q. -- of the document. So regardless, we're</p>	<p style="text-align: right;">Page 272</p> <p>1 Q. And similarly, the next sentence talks</p> <p>2 about percentage of chargeback requests for oxycodone</p> <p>3 30, and this sentence reads from 2009 through 2012,</p> <p>4 approximately 98 percent of the total volume by dosage</p> <p>5 unit of oxycodone 30-milligram products manufactured</p> <p>6 and distributed by Mallinckrodt fell under the</p> <p>7 chargeback system.</p> <p>8 Did I read that correctly?</p> <p>9 A. Yes.</p> <p>10 MR. O'CONNOR: Same objection.</p> <p>11 BY MR. KO:</p> <p>12 Q. So is it accurate to say that the vast</p> <p>13 majority of -- if not nearly 100 percent, of all</p> <p>14 oxycodone 15-milligram and oxycodone 30-milligram</p> <p>15 orders resulted in a chargeback request by a</p> <p>16 distributor --</p> <p>17 MR. O'CONNOR: Objection --</p> <p>18 BY MR. KO:</p> <p>19 Q. -- in the 2009 through 2012 time period?</p> <p>20 MR. O'CONNOR: Objection to form and</p> <p>21 scope.</p> <p>22 A. Not all, but vast majority.</p> <p>23 BY MR. KO:</p> <p>24 Q. Right. And I said, just so the record is</p>
<p style="text-align: right;">Page 271</p> <p>1 on Page 2 of this document.</p> <p>2 A. Okay. Thank you.</p> <p>3 Q. And there's a question asked, quote, what</p> <p>4 percentage of sales of oxycodone products involve</p> <p>5 customers that fall under the chargeback system.</p> <p>6 Did I read that correctly?</p> <p>7 A. Yes.</p> <p>8 Q. And the answer that's provided is from</p> <p>9 2009 through 2012, approximately 96 percent of the</p> <p>10 total volume by dosage units of oxycodone 15-milligram</p> <p>11 products manufactured and distributed by Mallinckrodt</p> <p>12 fell under the chargeback system.</p> <p>13 Did I read that correctly?</p> <p>14 A. Yes.</p> <p>15 Q. So a moment ago you had said not all</p> <p>16 requests -- not all -- sorry -- not all transactions</p> <p>17 resulted in a chargeback request?</p> <p>18 A. That's correct.</p> <p>19 Q. But at least with respect to oxycodone 15</p> <p>20 milligrams, from 2009 to 2012, 96 percent resulted in a</p> <p>21 chargeback request; is that accurate?</p> <p>22 MR. O'CONNOR: Objection to scope.</p> <p>23 A. Yes.</p> <p>24 BY MR. KO:</p>	<p style="text-align: right;">Page 273</p> <p>1 clear, is it accurate to say that nearly 100 percent of</p> <p>2 all oxycodone 15-milligram and oxycodone 30-milligram</p> <p>3 orders resulted in a chargeback request by a</p> <p>4 distributor?</p> <p>5 A. It would be --</p> <p>6 MR. O'CONNOR: Objection to form and</p> <p>7 scope.</p> <p>8 A. It would be more accurate to say 96</p> <p>9 percent and 98 percent.</p> <p>10 BY MR. KO:</p> <p>11 Q. Okay. Fair enough. So 96 percent of all</p> <p>12 oxy 15 orders of Mallinckrodt-manufactured oxy 15</p> <p>13 resulted in a chargeback request from the 2009 through</p> <p>14 2012 time period; correct?</p> <p>15 MR. O'CONNOR: Objection to form, scope.</p> <p>16 Asked and answered.</p> <p>17 A. Yes.</p> <p>18 BY MR. KO:</p> <p>19 Q. And final question. 98 percent of the</p> <p>20 total volume of oxycodone 30-milligram products</p> <p>21 manufactured by Mallinckrodt resulted in a chargeback</p> <p>22 request made by a distributor in the 2009 through 2012</p> <p>23 time period; correct?</p> <p>24 MR. O'CONNOR: Objection to form, scope.</p>

<p style="text-align: right;">Page 274</p> <p>1 Asked and answered.</p> <p>2 A. Correct.</p> <p>3 MR. KO: Okay. Those are all the</p> <p>4 questions I have. Thank you for your patience.</p> <p>5 A. Thank you.</p> <p>6 THE VIDEOGRAPHER: We are going off the</p> <p>7 record at 4:32 PM.</p> <p>8 [A brief recess was taken.]</p> <p>9 THE VIDEOGRAPHER: We are back on the</p> <p>10 record at 4:49 PM.</p> <p>11 EXAMINATION</p> <p>12 BY MS. HERZFELD:</p> <p>13 Q. Mr. Gillies, my name is Tricia Herzfeld,</p> <p>14 and I'm an attorney representing the plaintiffs in the</p> <p>15 Tennessee litigation. Are you familiar with the</p> <p>16 Tennessee litigation?</p> <p>17 A. Yes.</p> <p>18 Q. And what is it that you know about the</p> <p>19 Tennessee litigation?</p> <p>20 A. That you have a claim against Mallinckrodt</p> <p>21 and others for the opioid crisis.</p> <p>22 Q. What else do you know about it?</p> <p>23 A. That's about my recollection.</p> <p>24 Q. Do you know who the plaintiffs are in the</p>	<p style="text-align: right;">Page 276</p> <p>1 long period of time.</p> <p>2 A. I know. There were approximately four</p> <p>3 meetings and a videoconference during that time where</p> <p>4 issues were being discussed and Tennessee came up.</p> <p>5 Q. So the meetings and the videoconference,</p> <p>6 were they specifically about Tennessee?</p> <p>7 A. No.</p> <p>8 Q. Have you had any meetings or conversations</p> <p>9 with your counsel specifically about Tennessee?</p> <p>10 A. No.</p> <p>11 Q. So your discussions about Tennessee with</p> <p>12 your counsel, all told, would you say -- specifically</p> <p>13 about Tennessee -- how long?</p> <p>14 A. With counsel?</p> <p>15 Q. Yes, sir.</p> <p>16 A. Several hours.</p> <p>17 Q. Several hours?</p> <p>18 A. Yes.</p> <p>19 Q. And so you said several hours specifically</p> <p>20 about Tennessee?</p> <p>21 A. Correct.</p> <p>22 Q. Then you said several conversations</p> <p>23 between September 2018 and January 2019 were those</p> <p>24 other things and Tennessee was brought up, so I guess</p>
<p style="text-align: right;">Page 275</p> <p>1 Tennessee litigation?</p> <p>2 A. I do not recall.</p> <p>3 MS. HERZFELD: And before we get going in</p> <p>4 the deposition today, we're going to lodge our usual</p> <p>5 objections for failure to comply with the MDL protocol,</p> <p>6 which has also been entered and established in Dunaway</p> <p>7 (ph) cases.</p> <p>8 MR. O'CONNOR: And we're going to respond</p> <p>9 with our usual objection to your objections.</p> <p>10 MS. HERZFELD: There we go. Okay.</p> <p>11 BY MS. HERZFELD:</p> <p>12 Q. And Mr. Gillies, what did you do to</p> <p>13 prepare for the Tennessee portion of your deposition</p> <p>14 today?</p> <p>15 A. I met with legal counsel, and my</p> <p>16 recollection is that some of the documents that I</p> <p>17 reviewed might be associated with that matter.</p> <p>18 Q. How long would you say you met with your</p> <p>19 counsel specifically about the Tennessee matter?</p> <p>20 A. Several hours.</p> <p>21 Q. And when was that?</p> <p>22 A. Between September and -- September 2018</p> <p>23 and January 2019.</p> <p>24 Q. And so how was that broken up? That's a</p>	<p style="text-align: right;">Page 277</p> <p>1 I'm a little confused.</p> <p>2 A. Okay. So there were four meetings with</p> <p>3 counsel and a videoconference, and at some point during</p> <p>4 those meetings, some issues on Tennessee came up.</p> <p>5 Q. And so each of those meetings would you</p> <p>6 say was roughly how long?</p> <p>7 MS. MIKA: Sorry to interrupt the</p> <p>8 deposition, but you're muted.</p> <p>9 THE REPORTER: Okay, I just turned you</p> <p>10 guys back on.</p> <p>11 BY MS. HERZFELD:</p> <p>12 Q. I'm sorry. And so how long would you say</p> <p>13 each of those meetings was?</p> <p>14 A. So four of the meetings were approximately</p> <p>15 eight hours. The videoconference was four hours. And</p> <p>16 then combined, several hours over that time frame was</p> <p>17 devoted to Tennessee.</p> <p>18 Q. And who was on those calls?</p> <p>19 A. So on the call was Andrew O'Connor and</p> <p>20 Bill Davison.</p> <p>21 Q. Anybody else?</p> <p>22 A. No.</p> <p>23 Q. And what about in the meetings?</p> <p>24 A. In the meetings would have been Andrew,</p>

<p style="text-align: right;">Page 278</p> <p>1 Bill, and Josh.</p> <p>2 Q. Anybody else?</p> <p>3 A. No.</p> <p>4 Q. Have you read the Tennessee complaint?</p> <p>5 A. I don't think so.</p> <p>6 Q. And do you know if the allegations in the</p> <p>7 Tennessee complaint are meaningfully different than the</p> <p>8 allegations in the MDL?</p> <p>9 A. I do not.</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 BY MS. HERZFELD:</p> <p>12 Q. I'm sorry. You said I do not?</p> <p>13 A. That's correct.</p> <p>14 Q. And I'm sorry. I might have asked you</p> <p>15 this question before. Did you review any</p> <p>16 Tennessee-specific documents in preparation for your</p> <p>17 testimony today?</p> <p>18 A. I believe I reviewed some documents that</p> <p>19 related to Tennessee.</p> <p>20 Q. Are you finished?</p> <p>21 A. I am.</p> <p>22 Q. And when you looked at those documents,</p> <p>23 did they refresh your recollection in any way?</p> <p>24 A. Refresh my recollection of what?</p>	<p style="text-align: right;">Page 280</p> <p>1 Q. Did you search your e-mails or your</p> <p>2 documents for anything having to do with Tennessee</p> <p>3 prior to attending this deposition today?</p> <p>4 A. No.</p> <p>5 Q. Going to Topic 1. What was done by</p> <p>6 Mallinckrodt to ensure compliance with Tennessee state</p> <p>7 statutes and local laws?</p> <p>8 MR. O'CONNOR: Objection.</p> <p>9 MS. HERZFELD: What's the objection?</p> <p>10 MR. O'CONNOR: Form and potentially scope.</p> <p>11 Form for now.</p> <p>12 BY MS. HERZFELD:</p> <p>13 Q. Okay. I'm looking here. I just want</p> <p>14 to -- I want to be very clear. So looking at that very</p> <p>15 first topic, Topic 1 is your procedures, organization,</p> <p>16 and personnel assignments, oversight, due diligence,</p> <p>17 and quality control regarding compliance with the CSA</p> <p>18 and all state and local laws and regulations concerning</p> <p>19 the diversion of opioids. So I'll repeat the question.</p> <p>20 What was done by Mallinckrodt to ensure</p> <p>21 compliance with Tennessee state statutes and local laws</p> <p>22 regarding the manufacturing or distribution of opioids?</p> <p>23 MR. O'CONNOR: Objection to form.</p> <p>24 A. I don't know.</p>
<p style="text-align: right;">Page 279</p> <p>1 Q. Whatever the topic was of the document.</p> <p>2 A. Yes.</p> <p>3 Q. And how many documents that related to</p> <p>4 Tennessee would you say you reviewed?</p> <p>5 A. Less than five.</p> <p>6 Q. And what types of documents were they?</p> <p>7 MR. O'CONNOR: Object to work product,</p> <p>8 attorney-client privilege. You can answer at a high</p> <p>9 level.</p> <p>10 A. E-mails.</p> <p>11 BY MS. HERZFELD:</p> <p>12 Q. Just e-mails?</p> <p>13 A. That's all I can recall.</p> <p>14 Q. And were those e-mails selected for you by</p> <p>15 your counsel, or did you look at some on your own?</p> <p>16 A. Would have been presented to me in</p> <p>17 preparation from counsel.</p> <p>18 Q. And I believe you said you did some</p> <p>19 preparation outside of your preparation with counsel</p> <p>20 earlier; is that correct?</p> <p>21 A. Yes.</p> <p>22 Q. Did you focus any of that preparation time</p> <p>23 on the Tennessee litigation?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 281</p> <p>1 BY MS. HERZFELD:</p> <p>2 Q. Do you know if there were any policies in</p> <p>3 place to ensure compliance with Tennessee state and</p> <p>4 local laws regarding the manufacturing or distribution</p> <p>5 of opioids?</p> <p>6 A. I know there were some policies in place</p> <p>7 for some states. I'm not sure whether Tennessee fell</p> <p>8 within that.</p> <p>9 BY MS. HERZFELD:</p> <p>10 Q. Do you know which states you can recall?</p> <p>11 A. I do not.</p> <p>12 Q. Who would have been in charge of ensuring</p> <p>13 compliance with Tennessee state statutes and local laws</p> <p>14 regarding the manufacturing and distribution of</p> <p>15 controlled substances?</p> <p>16 A. I don't know.</p> <p>17 Q. And your answers are for 2008 forward?</p> <p>18 A. Yes.</p> <p>19 Q. And who would have been in charge for due</p> <p>20 diligence to ensure that Tennessee state and local laws</p> <p>21 were being followed with regard to manufacturing or</p> <p>22 distributing controlled substances in Tennessee?</p> <p>23 A. I don't know.</p> <p>24 Q. Did Mallinckrodt do anything to ensure</p>

<p style="text-align: right;">Page 282</p> <p>1 that it was in compliance with Tennessee code annotated 2 53-11-302, 303, and 304 concerning the manufacturing of 3 controlled substances? 4 A. I'm unfamiliar with those. 5 Q. And how are you familiar with those? 6 A. I said I'm unfamiliar with those. 7 Q. So my answer is (sic), here as 8 Mallinckrodt's corporate representative today, what did 9 Mallinckrodt do, if anything, to ensure compliance with 10 TCA 53-11-302, 303, and 304 regarding the manufacturing 11 or distribution of controlled substances? 12 A. And I'm sorry. What's the question there? 13 Q. I'll repeat it. 14 A. Okay. Thank you. 15 Q. Uh-huh. Did Mallinckrodt do anything to 16 ensure that it was in compliance with Tennessee code 17 annotated 53-11-303, 302, and 304, concerning the 18 manufacturing and distribution of controlled 19 substances? 20 A. I don't know. 21 Q. Did Mallinckrodt do anything to ensure it 22 was in compliance with Tennessee code annotated 23 53-11-401 regarding the distribution of controlled 24 substances?</p>	<p style="text-align: right;">Page 284</p> <p>1 Q. Do you recall any of the states that were? 2 A. I do not. 3 Q. Do you recall what area of the country 4 they were in? 5 A. I do not. 6 Q. Did Mallinckrodt do anything to monitor 7 the potential diversion of opioids in Tennessee 8 specifically? 9 A. It was a national program. 10 Q. But anything specifically about Tennessee? 11 A. Not that I'm aware of. 12 Q. What about auditing the -- or the 13 potential diversion of opioids in Tennessee? Did 14 Mallinckrodt do anything specifically for Tennessee in 15 auditing potential diversion of opioids in Tennessee? 16 MR. O'CONNOR: Objection to form. 17 A. Not that I'm aware of. 18 BY MS. HERZFELD: 19 Q. What about specific investigations of 20 potential diversion of opioids in Tennessee? Did 21 Mallinckrodt do anything specific -- strike that. I 22 got all caught up on that one. 23 Did Mallinckrodt do anything specifically 24 to investigate the potential diversion of its opioids</p>
<p style="text-align: right;">Page 283</p> <p>1 A. I don't know. 2 Q. Did Mallinckrodt do anything to ensure 3 that it was compliance with the Drug Dealer Liability 4 Act, Tennessee code annotated 29-38-101? 5 A. I don't know. 6 Q. What were -- did Mallinckrodt have 7 policies regarding the detection of potential diversion 8 of opioids in Tennessee? 9 A. We had a national program. 10 Q. And is that the national program that was 11 run by Karen Harper? 12 A. Yes. 13 Q. And she would have been in charge of that? 14 A. Yes. 15 Q. So she would have been the person with the 16 most knowledge outside of anyone? 17 MR. O'CONNOR: Objection to form. 18 MS. HERZFELD: You're right. I'll 19 withdraw the question. 20 BY MS. HERZFELD: 21 Q. Were there any specific policies regarding 22 potential diversion of opioids in Tennessee? 23 A. Again, there was on some states. I'm not 24 sure if Tennessee was one of those states.</p>	<p style="text-align: right;">Page 285</p> <p>1 in Tennessee? 2 A. Yes. 3 Q. What did you do? 4 A. I believe there were several 5 investigations that were brought to our attention by 6 law enforcement, and law enforcement was looking for 7 assistance, so we provided the assistance. 8 Q. Are you finished with your answer? 9 A. I am. 10 Q. And so you said there were several 11 investigations. What were they? 12 A. I'm not going to recall all of them. One 13 that sticks out is the Sunrise investigation. 14 Q. And were you involved in that? 15 A. No. 16 Q. And what was the extent of the involvement 17 of Tennessee law enforcement in the Sunrise 18 investigation, to your knowledge? 19 A. To my knowledge, that they had through 20 their investigation recovered a bottle of Mallinckrodt 21 product, and asked if there was anything that we could 22 do to identify where the bottle may have shipped to. 23 And so we -- first report we ran was the 24 lot number to see which distributors received that lot,</p>

<p style="text-align: right;">Page 286</p> <p>1 and then to further assist, they looked to see if there 2 was any other data in Mallinckrodt's possession that 3 might help law enforcement in this case, and they 4 looked at chargeback data. And because they had the 5 bottle, they were able to get some chargeback data that 6 led to Sunrise. 7 Q. What other investigations -- law 8 enforcement investigations in Tennessee are you aware 9 of? 10 A. Specifically, I can't recall at this time. 11 But there were -- it's my recollection that there were 12 some other law enforcement agencies that had contacted 13 us looking for similar information either on a lot 14 trace or the amount of active ingredient in one of our 15 pills. 16 Q. And if I was looking for documents about 17 those other investigations -- lot traces or the amount 18 of active ingredient in your pills -- where would I 19 find those documents? 20 A. Either with a search within our DEA 21 compliance or our security. 22 Q. And you're head of security; is that 23 right? 24 A. I am.</p>	<p style="text-align: right;">Page 288</p> <p>1 something that you need to object -- do you need to 2 have a privilege there? 3 A. Karen Harper. 4 Q. Okay. Karen Harper. Okay. And in that 5 investigation, does Morristown, Tennessee, ring a bell 6 to you? 7 A. It does not. 8 Q. So -- but in that investigation having to 9 do with Sunrise, those drugs were eventually traced 10 back to a Dr. Barry Schultz; is that correct? 11 A. That's correct. 12 Q. And Barry Schultz was a physician in 13 Florida; is that right? 14 A. That's correct. 15 Q. And he was running what some would 16 characterize as a pill mill; is that right? 17 MR. O'CONNOR: Objection. Form. 18 A. That's my understanding. 19 BY MS. HERZFELD: 20 Q. And so in that investigation what they 21 learned is that those pills went into the illegal drug 22 market along the Oxy Highway; is that right? 23 MR. O'CONNOR: Objection to form. 24 A. I'm sorry. Who's they that learned that?</p>
<p style="text-align: right;">Page 287</p> <p>1 Q. So have you personally been involved in 2 any? 3 A. I believe I have. 4 Q. And so you think those documents would 5 either be with DEA compliance group or in the security 6 group? They'd be stored there? 7 A. Correct. 8 Q. And going back to the Sunrise thing you 9 said before, was that investigation -- that was before 10 your time at Mallinckrodt? 11 A. Yes. 12 Q. And so how did you learn the information 13 about that investigation? 14 A. From legal counsel and Karen Harper. 15 Q. And when did you learn about it? 16 A. I'd say the first time -- can't recall, 17 but I'm going to say it was approximately 2014. 18 Q. And who told you about it in 2014? 19 A. Karen -- 20 MR. O'CONNOR: I'm going to object to the 21 extent it calls for attorney-client privilege 22 information. 23 BY MS. HERZFELD: 24 Q. Did your attorney tell you in 2014</p>	<p style="text-align: right;">Page 289</p> <p>1 BY MS. HERZFELD: 2 Q. Mallinckrodt learned that? 3 A. Oh, okay. 4 MR. O'CONNOR: Same objection. 5 A. So what did Mallinckrodt learn? 6 BY MS. HERZFELD: 7 Q. Yes, sir. 8 A. Okay. 9 Q. Would you like me to say that again? 10 A. Yeah, please. 11 Q. Sure. And so during the investigation 12 with law enforcement, Mallinckrodt learned that those 13 pills had come from the pill mill, Dr. Schultz, made it 14 into the illegal drug market, up the Oxy Highway; is 15 that correct? 16 MR. O'CONNOR: Objection. Form. 17 A. So define the Oxy Highway, and then -- 18 BY MS. HERZFELD: 19 Q. Up I-75. 20 A. Okay. Yes. 21 Q. And based on that investigation with law 22 enforcement in Tennessee, those illegal drugs made it 23 into the illegal drug market in Tennessee; is that 24 right?</p>

<p style="text-align: right;">Page 290</p> <p>1 MR. O'CONNOR: Objection to form.</p> <p>2 A. That's my understanding.</p> <p>3 BY MS. HERZFELD:</p> <p>4 Q. And that was Mallinckrodt's understanding</p> <p>5 at the time; is that right?</p> <p>6 MR. O'CONNOR: Same objection.</p> <p>7 A. That's correct.</p> <p>8 BY MS. HERZFELD:</p> <p>9 Q. And other than those two topics, the</p> <p>10 Sunrise investigation, and then when you said either</p> <p>11 lot traces or amount of active ingredients, can you</p> <p>12 think of any other communication that Mallinckrodt has</p> <p>13 had with Tennessee law enforcement specifically?</p> <p>14 A. I cannot.</p> <p>15 Q. What about any communication Mallinckrodt</p> <p>16 has had with Tennessee law enforcement generally? Can</p> <p>17 you recall any?</p> <p>18 A. No.</p> <p>19 Q. Did Mallinckrodt have any policies</p> <p>20 regarding the disclosure of suspicious orders in</p> <p>21 Tennessee to the DEA?</p> <p>22 A. I'm unaware of any suspicious orders to</p> <p>23 Tennessee.</p> <p>24 Q. And when you say unaware of any suspicious</p>	<p style="text-align: right;">Page 292</p> <p>1 DEA?</p> <p>2 A. Not that I'm aware of.</p> <p>3 Q. Did Mallinckrodt ever make any reports of</p> <p>4 suspected diversion to any Tennessee law enforcement?</p> <p>5 A. Not that I'm aware of.</p> <p>6 Q. Did Mallinckrodt ever make any reports of</p> <p>7 suspected diversion to federal law enforcement with</p> <p>8 jurisdiction over Tennessee, like the U.S. Attorney's</p> <p>9 office for Tennessee, for example?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. Yeah. So I'm unaware of any suspicious</p> <p>12 reports related to Tennessee that were reported to the</p> <p>13 DEA.</p> <p>14 BY MS. HERZFELD:</p> <p>15 Q. And when you say suspicious reports, do</p> <p>16 you also mean suspected diversion?</p> <p>17 A. Yes, because I'm unaware of any suspected</p> <p>18 diversion that Mallinckrodt was aware of taking place</p> <p>19 in Tennessee outside of that Sunrise matter and the</p> <p>20 doctor that was located in Florida.</p> <p>21 Q. And if there was suspected diversion in</p> <p>22 Tennessee, who would have been in charge of reporting</p> <p>23 that to Tennessee law enforcement?</p> <p>24 A. Security.</p>
<p style="text-align: right;">Page 291</p> <p>1 orders to Tennessee, do you mean shipped or meant for</p> <p>2 Tennessee?</p> <p>3 MR. O'CONNOR: Objection to form.</p> <p>4 BY MS. HERZFELD:</p> <p>5 Q. Well, I guess what do you mean when you</p> <p>6 say --</p> <p>7 A. Yeah. I mean --</p> <p>8 Q. -- you're unaware of any suspicious</p> <p>9 orders to Tennessee? What do you mean by that?</p> <p>10 A. Yeah. So I'm unaware that there were any</p> <p>11 suspicious orders reported to DEA that were intended</p> <p>12 for Tennessee.</p> <p>13 Q. And so to your knowledge there weren't any</p> <p>14 reports of suspicious orders to DEA about Tennessee?</p> <p>15 A. Right.</p> <p>16 Q. And who would have been in charge of</p> <p>17 making those reports if they had occurred?</p> <p>18 A. DEA compliance.</p> <p>19 Q. And who is head of DEA compliance?</p> <p>20 A. Karen Harper.</p> <p>21 Q. What about any reports of suspected</p> <p>22 diversion to the DEA -- I'm going to back up again.</p> <p>23 What about -- did Mallinckrodt ever make</p> <p>24 any reports of suspected diversion in Tennessee to the</p>	<p style="text-align: right;">Page 293</p> <p>1 Q. And security would have been you?</p> <p>2 A. Currently would be me, but -- time frame;</p> <p>3 right? So June 2012 on, law enforcement contact -- I</p> <p>4 was the main law enforcement contact for Mallinckrodt</p> <p>5 and had contact with federal, state, and local law</p> <p>6 enforcement across the country.</p> <p>7 Q. And before you it would have been Mr.</p> <p>8 Ratliff?</p> <p>9 A. Correct.</p> <p>10 Q. Did Mallinckrodt ever report to the DEA</p> <p>11 that it was limiting sales of anyone in Tennessee that</p> <p>12 they suspected of suspicious orders?</p> <p>13 A. So I can't recall any sales of our</p> <p>14 products to distributors in Tennessee. So can you</p> <p>15 restate -- just repeat your question?</p> <p>16 Q. Sure. Sure. I'll kind of rephrase it.</p> <p>17 I guess I'm wondering if you know if</p> <p>18 Mallinckrodt ever reported to the DEA of halting of</p> <p>19 sales to anyone involved in suspicious orders in</p> <p>20 Tennessee.</p> <p>21 A. No.</p> <p>22 Q. I'm going to back up a little bit, too.</p> <p>23 And when I'm saying sales, I don't just mean to the</p> <p>24 distributors. Also based on chargeback data. You had</p>

<p style="text-align: right;">Page 294</p> <p>1 access to chargeback data at Mallinckrodt; is that 2 correct?</p> <p>3 MR. O'CONNOR: Objection to form.</p> <p>4 A. But those weren't our sales. The sales 5 were from -- those sales to the pharmacies would have 6 been from the distributors.</p> <p>7 BY MS. HERZFELD:</p> <p>8 Q. And I --</p> <p>9 A. Did we have chargeback data? Yes. Those 10 were retroactive.</p> <p>11 Q. So I'm going to back up my questions a 12 little bit.</p> <p>13 So to your knowledge there weren't any 14 distributors in Tennessee that Mallinckrodt was selling 15 opioid products to? Is that your testimony?</p> <p>16 A. That I can recall. Correct.</p> <p>17 Q. And so I shouldn't have said sales, 18 perhaps.</p> <p>19 So when we're talking about the shipping 20 of Mallinckrodt opioids that end up to people in 21 Tennessee, Mallinckrodt would have some of that 22 information via chargeback data; is that correct?</p> <p>23 A. Correct.</p> <p>24 MR. O'CONNOR: Objection to form.</p>	<p style="text-align: right;">Page 296</p> <p>1 Q. And so I guess my question is a little bit 2 more basic.</p> <p>3 A. Okay.</p> <p>4 Q. Mallinckrodt could do chargeback 5 restrictions; is that right?</p> <p>6 A. Yes.</p> <p>7 Q. And chargeback restrictions would then 8 give a financial incentive for the distributor not to 9 do business with that particular pharmacy; is that 10 correct?</p> <p>11 A. Can you repeat that question? Because I 12 think --</p> <p>13 Q. Do I have it backwards?</p> <p>14 A. I think so.</p> <p>15 Q. So the chargeback restriction would give a 16 financial incentive for the distributor not to do 17 business with that pharmacy; is that right?</p> <p>18 A. I'm wondering if you're still getting that 19 wrong. A financial incentive not to sell?</p> <p>20 Q. Okay. I'm going to back up.</p> <p>21 A. Okay.</p> <p>22 Q. Explain to me your understanding of a 23 chargeback. Let's start there.</p> <p>24 A. So it's --</p>
<p style="text-align: right;">Page 295</p> <p>1 BY MS. HERZFELD:</p> <p>2 Q. And based on that chargeback data, 3 Mallinckrodt would sometimes put different pharmacies 4 on chargeback restrictions; is that right?</p> <p>5 A. That's correct.</p> <p>6 Q. And so based on those chargeback 7 restrictions, did Mallinckrodt ever report the limiting 8 of the ability to process chargebacks for pharmacies in 9 Tennessee?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. So I'm sorry. I'm not sure I understand 12 that question.</p> <p>13 BY MS. HERZFELD:</p> <p>14 Q. Sure.</p> <p>15 A. So are you asking me did we restrict a 16 pharmacy in Tennessee? Is that the question?</p> <p>17 Q. It's not.</p> <p>18 A. Okay.</p> <p>19 Q. But sure, do you know if you did?</p> <p>20 A. I don't recall, but I know the records 21 were provided of all the pharmacies that were 22 chargeback restricted.</p> <p>23 Q. In Tennessee?</p> <p>24 A. For the entire country.</p>	<p style="text-align: right;">Page 297</p> <p>1 MR. O'CONNOR: Objection to scope.</p> <p>2 A. It's a contractual relationship between 3 Mallinckrodt and its customers, distributors and 4 wholesalers. After they've bought the product, if they 5 sell it to one of their customers for less than what 6 they bought it, they can charge back that difference to 7 us.</p> <p>8 BY MS. HERZFELD:</p> <p>9 Q. And if Mallinckrodt put somebody on a 10 chargeback restriction, what is the impact that that 11 has for the wholesaler?</p> <p>12 MR. O'CONNOR: Objection to form.</p> <p>13 A. It could be a financial disincentive, 14 because if they continue to sell to the pharmacy they 15 would not be made whole.</p> <p>16 BY MS. HERZFELD:</p> <p>17 Q. So that is one way that Mallinckrodt would 18 deal with its customers' customers, is chargeback 19 restrictions; is that right?</p> <p>20 MR. O'CONNOR: Objection to form.</p> <p>21 A. One way Mallinckrodt could deal with its 22 customer's customer, by chargeback restricting them?</p> <p>23 BY MS. HERZFELD:</p> <p>24 Q. Yes, sir.</p>

<p style="text-align: right;">Page 298</p> <p>1 A. Yes.</p> <p>2 Q. Was there ever anything between chargeback</p> <p>3 restrictions, like a chargeback limiting?</p> <p>4 MR. O'CONNOR: Objection to form.</p> <p>5 A. I don't even know what that means. I'm</p> <p>6 sorry.</p> <p>7 BY MS. HERZFELD:</p> <p>8 Q. So did you ever -- did Mallinckrodt ever</p> <p>9 attempt to limit the sale of or the distribution of --</p> <p>10 I'm going to back up. Strike that. Start over.</p> <p>11 Did Mallinckrodt ever try to limit the</p> <p>12 volume of its products, its opioid products, to</p> <p>13 particular pharmacies?</p> <p>14 A. So we didn't sell to the pharmacies; the</p> <p>15 distributors did.</p> <p>16 Q. I understand.</p> <p>17 A. Okay.</p> <p>18 Q. But you could disincentivize the</p> <p>19 distributors from doing business with pharmacies by</p> <p>20 implementing chargeback restrictions.</p> <p>21 That's what we've established; right?</p> <p>22 A. We wouldn't know which pharmacies the</p> <p>23 distributors were selling to unless we looked at the</p> <p>24 chargeback data.</p>	<p style="text-align: right;">Page 300</p> <p>1 that's all you would do if you had a suspicion that a</p> <p>2 pharmacy based on information that you had might be</p> <p>3 engaged in diversion?</p> <p>4 Did I understand that correctly?</p> <p>5 MR. O'CONNOR: Objection to form.</p> <p>6 A. Yeah, could you restate that one more</p> <p>7 time?</p> <p>8 BY MS. HERZFELD:</p> <p>9 Q. Sure. So I think from your explanation</p> <p>10 that you just gave me is you said if you, based on the</p> <p>11 information Mallinckrodt had, suspected that a pharmacy</p> <p>12 might be engaged in diversion, you would notify the</p> <p>13 distributor that you would be placing that pharmacy on</p> <p>14 chargeback restriction.</p> <p>15 Did I understand that correctly?</p> <p>16 A. That's correct. We would notify the DEA</p> <p>17 and all distributors that -- so you might be the only</p> <p>18 distributor providing product, but we would notify the</p> <p>19 DEA and all distributors that we were chargeback</p> <p>20 restricting that pharmacy.</p> <p>21 Q. And when did that begin?</p> <p>22 A. The earliest I recall was 2011.</p> <p>23 Q. And was that notifying the DEA in 2011 or</p> <p>24 notifying all the distributors in 2011?</p>
<p style="text-align: right;">Page 299</p> <p>1 Q. Okay, but that's not my question.</p> <p>2 A. Okay. Then I'm confused by what you're</p> <p>3 trying to ask me on this.</p> <p>4 Q. So what I'm say --</p> <p>5 A. Because we sell to distributors and the</p> <p>6 wholesalers, and you're asking me to reduce product to</p> <p>7 the pharmacy that I'm not selling to. That's how I</p> <p>8 understood your question.</p> <p>9 Q. So what do you understand the purpose of</p> <p>10 chargeback restrictions to be?</p> <p>11 A. So if we think there's a potential for</p> <p>12 diversion based on the information that we've seen,</p> <p>13 then we restrict the chargebacks, advising the</p> <p>14 distributors that we have an issue with this pharmacy.</p> <p>15 So if they want to continue to sell, they,</p> <p>16 the distributors or wholesalers, that's on them, but</p> <p>17 we're not going to give them the chargeback. So the</p> <p>18 restriction comes from we not paying the distributors</p> <p>19 and the wholesalers that difference.</p> <p>20 That's the piece there, and it has nothing</p> <p>21 to do with the pharmacy, because we won't know which</p> <p>22 pharmacy that is until weeks or a month or longer</p> <p>23 later.</p> <p>24 Q. And so other than chargeback restrictions,</p>	<p style="text-align: right;">Page 301</p> <p>1 A. Both.</p> <p>2 MR. O'CONNOR: Objection.</p> <p>3 BY MS. HERZFELD:</p> <p>4 Q. And so I guess my question is, other than</p> <p>5 that process which you've just explained, was there</p> <p>6 anything else you would do if you suspected a potential</p> <p>7 pharmacy was engaging in diversion?</p> <p>8 A. If we did suspect, we'd contact law</p> <p>9 enforcement.</p> <p>10 Q. And which law enforcement? The DEA?</p> <p>11 A. DEA, the applicable state or local agency.</p> <p>12 Q. And where would I find records of those</p> <p>13 contacts with state or local agencies?</p> <p>14 A. Well, first of all, you would have -- if</p> <p>15 the record existed, it would be in security's files.</p> <p>16 But I'm not saying that there are any that exist.</p> <p>17 Q. Is there a reason that there wouldn't be</p> <p>18 ones that exist?</p> <p>19 A. Yeah, because we didn't have any</p> <p>20 information that a particular pharmacy was involved in</p> <p>21 diversion.</p> <p>22 Q. Can you recall a time when you had</p> <p>23 information that a particular pharmacy was involved in</p> <p>24 diversion?</p>

<p style="text-align: right;">Page 302</p> <p>1 A. I can recall a time when there were</p> <p>2 pharmacies that I had concern about, and I notified the</p> <p>3 DEA on that.</p> <p>4 Q. Is that all?</p> <p>5 A. Yes.</p> <p>6 Q. Does Mallinckrodt to your knowledge have</p> <p>7 any suspicious order monitoring policies and procedures</p> <p>8 that are specific to Tennessee?</p> <p>9 A. No, it's a national program.</p> <p>10 Q. I'm going to show you what we will mark</p> <p>11 here as Plaintiff's Exhibit 31.</p> <p>12 [Exhibit Mallinckrodt-Gillies-031</p> <p>13 marked for identification.]</p> <p>14 Q. I don't like to use the ELMO.</p> <p>15 A. Really?</p> <p>16 Q. Do you want me to use -- I can use it if</p> <p>17 you want me to use it, but for me I don't use it.</p> <p>18 Okay. Here. Ooh, it's really small. Yeah, I can see</p> <p>19 why.</p> <p>20 THE VIDEOGRAPHER: Can you see?</p> <p>21 MS. HERZFELD: Can you see? How's that?</p> <p>22 THE VIDEOGRAPHER: Here you go.</p> <p>23 BY MS. HERZFELD:</p> <p>24 Q. That's good. Is that better?</p>	<p style="text-align: right;">Page 304</p> <p>1 A. Okay.</p> <p>2 Q. Am I right in that?</p> <p>3 MR. O'CONNOR: Objection to scope.</p> <p>4 A. I mean, I'm uncertain, but it says</p> <p>5 department, legal, and stuff, and the purpose and the</p> <p>6 file path. I mean, it looks like folders within a</p> <p>7 computer system.</p> <p>8 BY MS. HERZFELD:</p> <p>9 Q. And do you have any way of knowing if this</p> <p>10 is a complete listing of the files in the computer</p> <p>11 system?</p> <p>12 MR. O'CONNOR: Objection to scope.</p> <p>13 A. I have no idea.</p> <p>14 BY MS. HERZFELD:</p> <p>15 Q. And when you say that documents would be</p> <p>16 in security, for example --</p> <p>17 A. Uh-huh.</p> <p>18 Q. -- there's a security folder at</p> <p>19 Mallinckrodt?</p> <p>20 A. Yes.</p> <p>21 Q. And that would look something like one of</p> <p>22 these? It's not like a filing cabinet; it's like a</p> <p>23 computer path?</p> <p>24 A. That's correct.</p>
<p style="text-align: right;">Page 303</p> <p>1 A. Could you blow that up? Yeah, that --</p> <p>2 THE VIDEOGRAPHER: That's as big as it</p> <p>3 gets.</p> <p>4 A. Okay.</p> <p>5 BY MS. HERZFELD:</p> <p>6 Q. When we all get over a certain age, it</p> <p>7 makes it difficult to see. Okay. Okay. If you'll</p> <p>8 take a look at this document.</p> <p>9 A. I'm not going to be able to see it here.</p> <p>10 So can you just --</p> <p>11 Q. Just -- you can see it from there.</p> <p>12 A. Okay.</p> <p>13 Q. Yeah. Okay. I'm just going to show you</p> <p>14 this document here, and this is a document that's been</p> <p>15 produced to us in discovery.</p> <p>16 A. Okay.</p> <p>17 Q. Can you tell from this document what it</p> <p>18 appears to be?</p> <p>19 A. I mean, it appears to be a search of files</p> <p>20 that they're providing.</p> <p>21 Q. And so when I look at this document, it</p> <p>22 looks to me like it's a printout of all the different</p> <p>23 kinds of places where documents are maybe stored on a</p> <p>24 server, like an internal Mallinckrodt server.</p>	<p style="text-align: right;">Page 305</p> <p>1 Q. Okay. That's my only question to that.</p> <p>2 A. Okay.</p> <p>3 Q. Thank you. Okay. Moving on to Exhibit</p> <p>4 32.</p> <p>5 [Exhibit Mallinckrodt-Gillies-032</p> <p>6 marked for identification.]</p> <p>7 Q. This one's a little bit easier to see.</p> <p>8 Okay.</p> <p>9 A. Okay.</p> <p>10 Q. Have you seen this document before?</p> <p>11 A. I believe I have.</p> <p>12 Q. And it looks like at the bottom it says</p> <p>13 it's the DEA distributor conference PowerPoint from</p> <p>14 September 23rd, 2015. Is that correct?</p> <p>15 A. Yes.</p> <p>16 Q. And I think you were talking before about</p> <p>17 different DEA conferences that occur throughout the</p> <p>18 years. Is that right?</p> <p>19 A. Yes.</p> <p>20 Q. And did you ever attend those DEA</p> <p>21 conferences?</p> <p>22 A. Put on by DEA? No. Put on by others?</p> <p>23 Yes.</p> <p>24 Q. And if somebody from Mallinckrodt attended</p>

<p style="text-align: right;">Page 306</p> <p>1 those conferences from DEA, they would bring back</p> <p>2 information to the team; is that right?</p> <p>3 A. That's right.</p> <p>4 Q. And is that how this PowerPoint made it</p> <p>5 back from this conference to Mallinckrodt?</p> <p>6 A. I don't know how it made it back, so --</p> <p>7 Q. But you've seen it before?</p> <p>8 A. I believe I have.</p> <p>9 Q. If you'll flip through with me here.</p> <p>10 A. Okay.</p> <p>11 Q. To -- there aren't really any pages on it.</p> <p>12 A. Okay.</p> <p>13 Q. There aren't page numbers. It's about --</p> <p>14 one that says at the bottom MNK_TNSTA00607267. It's</p> <p>15 the first map. If you'll take a look at that for me,</p> <p>16 please.</p> <p>17 A. Yes.</p> <p>18 Q. You see where I'm at?</p> <p>19 A. Yes.</p> <p>20 Q. Could you please tell me what the title of</p> <p>21 this map is?</p> <p>22 A. 2007 Tennessee opioid prescriptions.</p> <p>23 Q. And that's showing prescription rate per</p> <p>24 hundred population; is that right?</p>	<p style="text-align: right;">Page 308</p> <p>1 that right?</p> <p>2 A. Correct.</p> <p>3 Q. And does there appear to be more darkened</p> <p>4 shades on the 2009 than there were on the 2008?</p> <p>5 MR. O'CONNOR: Objection to form.</p> <p>6 A. Yes.</p> <p>7 BY MS. HERZFELD:</p> <p>8 Q. If you'll flip with me to the next page.</p> <p>9 If you could give me the title there, please.</p> <p>10 A. 2010 Tennessee opioid prescriptions.</p> <p>11 Q. And this also shows the prescription rate</p> <p>12 per hundred population, with the darkest number being</p> <p>13 the highest; is that correct?</p> <p>14 A. Correct.</p> <p>15 Q. And does 2010's map look darker in some</p> <p>16 sections than 2009?</p> <p>17 MR. O'CONNOR: Objection to form.</p> <p>18 A. Yes.</p> <p>19 BY MS. HERZFELD:</p> <p>20 Q. If you'll flip with me to the next page,</p> <p>21 please. What is the title of that page?</p> <p>22 A. 2011 Tennessee opioid prescriptions.</p> <p>23 Q. And this it says here is a map of</p> <p>24 Tennessee, with the darkest colors being the highest</p>
<p style="text-align: right;">Page 307</p> <p>1 A. Yes.</p> <p>2 Q. Flip with me to the next page, please.</p> <p>3 Could you tell me the title there?</p> <p>4 A. 2008 Tennessee opioid prescriptions.</p> <p>5 Q. And that's also showing prescription rates</p> <p>6 per hundred population; is that right?</p> <p>7 A. Yes.</p> <p>8 Q. And the highest prescription rate is the</p> <p>9 darkest color; is that right?</p> <p>10 A. Yes.</p> <p>11 Q. And from the 2007 page to 2008 page, do</p> <p>12 you agree that there are more darkened colors in 2008</p> <p>13 than there were in 2007?</p> <p>14 MR. O'CONNOR: Objection to form.</p> <p>15 A. Yes.</p> <p>16 BY MS. HERZFELD:</p> <p>17 Q. If you'll flip with me to the next page,</p> <p>18 please. Could you read the title there for me, please?</p> <p>19 A. 2009 Tennessee opioid prescriptions.</p> <p>20 Q. And that also is a prescription rate per</p> <p>21 hundred population; is that right?</p> <p>22 A. Correct.</p> <p>23 Q. And the darkened number is the highest</p> <p>24 number of prescription rates per hundred population; is</p>	<p style="text-align: right;">Page 309</p> <p>1 rate of prescription per hundred population; is that</p> <p>2 correct?</p> <p>3 A. Correct.</p> <p>4 Q. And would you agree that the 2011 map</p> <p>5 looks darker than the 2010 map?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. Yes.</p> <p>8 BY MS. HERZFELD:</p> <p>9 Q. And if you look at the 2007 map compared</p> <p>10 to the 2011 map.</p> <p>11 Based on these two documents, would you</p> <p>12 say the prescription rate for opioids per hundred</p> <p>13 population in Tennessee went up?</p> <p>14 A. Yes.</p> <p>15 Q. If you'll flip with me to the next page,</p> <p>16 the one at the bottom that says 607272. Could you read</p> <p>17 the title of that page for me, please?</p> <p>18 A. Painkiller prescriptions by state.</p> <p>19 Q. Okay. Could you read the rest of the</p> <p>20 slide for me here?</p> <p>21 A. In 2012, southern states had the most per</p> <p>22 person. The top three states were Alabama, Tennessee,</p> <p>23 and West Virginia. Alabama, 143 per hundred people.</p> <p>24 Tennessee, 143 per hundred people. West Virginia, 138</p>

<p style="text-align: right;">Page 310</p> <p>1 per hundred people. Lowest, Hawaii, 52 per hundred 2 people. 3 Q. If you'll switch with me to the next page, 4 please. Read the title of that page for me. 5 A. Tennessee pain clinics, 2014. 6 Q. And this shows that there are 307 7 certified clinics within Tennessee; is that right? 8 A. That's what it says, yes. 9 Q. And it breaks it down by counties; is that 10 right? 11 A. Yes. 12 Q. If you'll flip with me to the next page, 13 724 -- 7274. Okay. If you could tell me what the 14 title of this page is, please. 15 A. Tennessee top 10 controlled substances, 16 2014. 17 Q. And what is the top controlled substance 18 for Tennessee in 2014, according to this chart? 19 A. Hydrocodone products. 20 Q. And the second? 21 A. Alprazolam. 22 Q. And the third? 23 A. Oxycodone. 24 Q. And does Mallinckrodt produce oxycodone?</p>	<p style="text-align: right;">Page 312</p> <p>1 Q. Where it says crime? 2 A. Drug-related crimes have increased 33 3 percent from 2005 to 2012. Lost productivity, 4 prescription drug abuse cost was estimated at \$143 5 million in 2008. Adjusted for inflation, it's now \$160 6 million. 7 Q. And if you'll switch with me then to the 8 next -- the page at the bottom that's 7277. Could you 9 read the title of that page for me, please? 10 A. Unlawful distribution. 11 Q. And the first line it says is 12 inappropriate or overprescribing. Would you agree that 13 that is unlawful distribution of opioids? 14 MR. O'CONNOR: Objection to form. 15 A. If there wasn't a legitimate medical 16 purpose. 17 BY MS. HERZFELD: 18 Q. What about knowledge of redistribution? 19 Would that constitute unlawful distribution of opioids? 20 MR. O'CONNOR: Objection to form. 21 A. So just so that I'm clear, what are we 22 saying knowledge of redistribution is? 23 BY MS. HERZFELD: 24 Q. Knowledge of redistribution of an opioid</p>
<p style="text-align: right;">Page 311</p> <p>1 A. Yes. 2 Q. And does Mallinckrodt produce hydrocodone? 3 A. Yes. 4 Q. If you'll switch to the next one for me, 5 please, the one at the bottom that says 7275. Read the 6 top of the page for me, please. 7 A. Impact in Tennessee. 8 Q. And then what is the next line that starts 9 with deaths? 10 A. Deaths. Over 1,000 people are dying from 11 in the state every year. 12 Q. And the next one that starts with 13 children? 14 A. Children. 50 percent of the children in 15 DCS care are there because of parental drug abuse. 16 Over the past decade, there's been a tenfold rise in 17 the incidence of babies born with neonatal abstinence 18 syndrome. 19 Q. And the one that says health care costs? 20 A. Health care costs. ER visits for 21 overdoses have increased 40 percent from 2005 to 2010. 22 Estimated cost of providing drug treatment to Tennessee 23 drug abusers living below the poverty line is \$28 24 million.</p>	<p style="text-align: right;">Page 313</p> <p>1 without a legitimate medical purpose. 2 MR. O'CONNOR: Objection to form. Same 3 objection. 4 A. So somebody's redistributing the product 5 for a nonmedical purpose or a scientific purpose; 6 right? 7 BY MS. HERZFELD: 8 Q. Or a drug abuse purpose? 9 A. Or doing it for a drug abuse purpose? 10 Q. Yes, sir. 11 A. Okay. 12 Q. Would you consider that to be unlawful 13 distribution of an opioid product? 14 MR. O'CONNOR: Objection. Form. 15 A. It would be diversion of the product. 16 BY MS. HERZFELD: 17 Q. And is diversion of the product unlawful? 18 A. And it could be. 19 Q. Lax or careless prescription practices. 20 Could that be indicative of unlawful distribution? 21 MR. O'CONNOR: Objection to form. 22 A. I don't know what that relates to, but it 23 could be. 24 BY MS. HERZFELD:</p>

<p style="text-align: right;">Page 314</p> <p>1 Q. What about people who are doctor shoppers?</p> <p>2 Could that indicate unlawful distribution?</p> <p>3 MR. O'CONNOR: Objection to form.</p> <p>4 A. It could be somebody that's involved in</p> <p>5 the illicit drug trade.</p> <p>6 BY MS. HERZFELD:</p> <p>7 Q. And prescription rings would be</p> <p>8 prescription drug rings. That would be an unlawful</p> <p>9 distribution of opioids; is that correct?</p> <p>10 MR. O'CONNOR: Objection to form.</p> <p>11 A. Yes.</p> <p>12 BY MS. HERZFELD:</p> <p>13 Q. You can switch with me on -- oops. Losing</p> <p>14 myself here. Okay. If you'll switch with me to the</p> <p>15 one at the bottom that says 7286. It says United</p> <p>16 States versus Lang. Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. And this says Superior One Medical Clinic.</p> <p>19 Do you know where Superior One Medical Clinic is</p> <p>20 located?</p> <p>21 A. I do not.</p> <p>22 Q. If I told you it was in Tennessee, would</p> <p>23 you have any reason to doubt that?</p> <p>24 MR. O'CONNOR: Objection to form.</p>	<p style="text-align: right;">Page 316</p> <p>1 A. I'll take your comment that that's</p> <p>2 accurate.</p> <p>3 BY MS. HERZFELD:</p> <p>4 Q. Is that what the page shows?</p> <p>5 A. It shows names, ages, and then I'm making</p> <p>6 the assumption that that's their sentencing and how it</p> <p>7 either occurred through a plea or trial.</p> <p>8 Q. So based on these documents that we've</p> <p>9 looked at, was Mallinckrodt aware that there was an</p> <p>10 opioid crisis in Tennessee?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. As I've stated earlier, Mallinckrodt</p> <p>13 became aware of the scope of the opioid crisis after</p> <p>14 our meeting with the DEA in August of 2011.</p> <p>15 BY MS. HERZFELD:</p> <p>16 Q. And Mallinckrodt was aware that there was</p> <p>17 an opioid crisis in Tennessee as well; is that correct?</p> <p>18 MR. O'CONNOR: Objection to form.</p> <p>19 A. I don't know that.</p> <p>20 BY MS. HERZFELD:</p> <p>21 Q. If you'll switch with me to the page here</p> <p>22 in this one last one here, 7310, the second to third</p> <p>23 back. Okay. Could you read the title of that page for</p> <p>24 me, please?</p>
<p style="text-align: right;">Page 315</p> <p>1 A. I don't think you would mislead me.</p> <p>2 BY MS. HERZFELD:</p> <p>3 Q. I'm going to just flip through this to</p> <p>4 make this a little bit quicker. Okay. On the one at</p> <p>5 the bottom that says 7288. Okay. Can you read me the</p> <p>6 title of that document, please?</p> <p>7 A. Oxycodone's street value is based on</p> <p>8 prescriptions.</p> <p>9 Q. Are you aware that there is a street value</p> <p>10 for oxycodone?</p> <p>11 MR. O'CONNOR: Objection to form.</p> <p>12 A. Yes.</p> <p>13 BY MS. HERZFELD:</p> <p>14 Q. And if you'll switch with me almost all</p> <p>15 the way here to the back. The one that's 7309. My</p> <p>16 apologies. Okay. Could you read the top of that title</p> <p>17 for me?</p> <p>18 A. More east Tennessee pill defendants.</p> <p>19 Q. And this indicates -- one, two, three,</p> <p>20 four, five, six, seven, eight, nine, 10, 11, 12 -- 12</p> <p>21 people who pled guilty or were found guilty of some</p> <p>22 crime involving pills in east Tennessee, according to</p> <p>23 this chart; is that correct?</p> <p>24 MR. O'CONNOR: Objection.</p>	<p style="text-align: right;">Page 317</p> <p>1 A. Red flags.</p> <p>2 Q. And red flags that are indicated by this</p> <p>3 DEA PowerPoint here -- the first one is complaints.</p> <p>4 Did Mallinckrodt consider complaints to be a red flag</p> <p>5 of diversion?</p> <p>6 MR. O'CONNOR: Objection to form.</p> <p>7 A. Mallinckrodt considered certain red flags.</p> <p>8 I'm not sure what the complaint is referencing here on</p> <p>9 this page. So --</p> <p>10 BY MS. HERZFELD:</p> <p>11 Q. I'll rephrase the question. When</p> <p>12 Mallinckrodt was looking for red flags of diversion,</p> <p>13 would Mallinckrodt look for complaints about a</p> <p>14 particular location?</p> <p>15 A. So --</p> <p>16 MR. O'CONNOR: Objection to form.</p> <p>17 A. Complaints against a pharmacy?</p> <p>18 BY MS. HERZFELD:</p> <p>19 Q. Sure.</p> <p>20 A. Yes.</p> <p>21 Q. Complaints about a doctor?</p> <p>22 A. Yes.</p> <p>23 Q. Complaints about there being a pill mill</p> <p>24 someplace?</p>

<p style="text-align: right;">Page 318</p> <p>1 MR. O'CONNOR: Objection to form.</p> <p>2 A. Yes.</p> <p>3 BY MS. HERZFELD:</p> <p>4 Q. What about form of payment? Is form of</p> <p>5 payment something that Mallinckrodt would look at?</p> <p>6 A. Yes.</p> <p>7 Q. What about the types of customers? Is</p> <p>8 that something Mallinckrodt would look at?</p> <p>9 A. So again, our customers are the</p> <p>10 distributors and the wholesalers, so I'm assuming on</p> <p>11 this page this is talking about customers to the</p> <p>12 pharmacy.</p> <p>13 Do you know? Because I don't know what</p> <p>14 types of customers here, but our customers are the</p> <p>15 wholesalers and distributors. So -- I don't know how</p> <p>16 they're defining types of customers here, so it's hard</p> <p>17 for me to answer that question.</p> <p>18 Q. So when we said before form of payment is</p> <p>19 something that Mallinckrodt would look at to indicate</p> <p>20 diversion, is that form of payment of the distributor?</p> <p>21 A. No, in that case, working through the</p> <p>22 distributors and the wholesalers, we would learn</p> <p>23 whether there's a high percentage of cash being paid</p> <p>24 for products. So from that perspective, that's one of</p>	<p style="text-align: right;">Page 320</p> <p>1 sales? Is that one of the routine things Mallinckrodt</p> <p>2 would look for through its wholesalers or distributors?</p> <p>3 MR. O'CONNOR: Objection to form.</p> <p>4 A. So again, our sales are to the</p> <p>5 distributors and wholesalers. In our chargeback</p> <p>6 review, if we saw an increase in sales, we would ask</p> <p>7 for an explanation from the distributors or the</p> <p>8 wholesalers.</p> <p>9 BY MS. HERZFELD:</p> <p>10 Q. And that's how the process goes now?</p> <p>11 A. That is how the process is, yes.</p> <p>12 Q. And is that how the process has been the</p> <p>13 entire time you've been at Mallinckrodt?</p> <p>14 A. Yes.</p> <p>15 Q. And when you would communicate with</p> <p>16 Mallinckrodt about some of these types of things -- you</p> <p>17 said you would get that information through your</p> <p>18 distributors or wholesalers.</p> <p>19 When they gave you that information, would</p> <p>20 Mallinckrodt do anything to verify that information, or</p> <p>21 would you just accept what your wholesalers or</p> <p>22 distributors tell you?</p> <p>23 MR. O'CONNOR: Objection to form.</p> <p>24 A. So can you repeat that question?</p>
<p style="text-align: right;">Page 319</p> <p>1 the red flags we would be looking for.</p> <p>2 Q. And would you look through the</p> <p>3 distributors or wholesalers for the types of customers?</p> <p>4 A. No.</p> <p>5 Q. Would you look through the distributors or</p> <p>6 wholesalers for the type of location?</p> <p>7 MR. O'CONNOR: Object to form.</p> <p>8 A. So if the distributor or wholesaler --</p> <p>9 actually, if Mallinckrodt became concerned about a</p> <p>10 pharmacy, we would do some research on the location of</p> <p>11 that pharmacy.</p> <p>12 But again, I don't know what they mean by</p> <p>13 type of location, so I don't know how to fully reply to</p> <p>14 that question without knowing what he meant or she</p> <p>15 meant when she wrote type of location.</p> <p>16 BY MS. HERZFELD:</p> <p>17 Q. Is that -- is the type of location for</p> <p>18 where a pharmacy is located, is that something that</p> <p>19 Mallinckrodt would request information of routinely</p> <p>20 from his wholesalers or distributors?</p> <p>21 A. No.</p> <p>22 MR. O'CONNOR: Objection to form.</p> <p>23 BY MS. HERZFELD:</p> <p>24 Q. What about an unexplained increase in</p>	<p style="text-align: right;">Page 321</p> <p>1 BY MS. HERZFELD:</p> <p>2 Q. Sure.</p> <p>3 A. Just so I completely understand it. Yeah.</p> <p>4 Q. Yeah. I'm going to try not to go through</p> <p>5 the whole list, because --</p> <p>6 A. Okay.</p> <p>7 Q. But you had said before that when we were</p> <p>8 talking about some of these questions --</p> <p>9 A. Uh-huh.</p> <p>10 Q. -- you would try to -- Mallinckrodt would</p> <p>11 try to get that information through its wholesalers or</p> <p>12 distributors in some circumstances. Did I characterize</p> <p>13 your testimony fairly?</p> <p>14 A. Yeah, if we became aware of a pharmacy</p> <p>15 that we should be concerned about. Okay.</p> <p>16 Q. But absent somebody making you aware of</p> <p>17 something you should -- Mallinckrodt would be concerned</p> <p>18 about with a particular pharmacy, you didn't routinely</p> <p>19 check on these things for your customer's customer; is</p> <p>20 that right?</p> <p>21 MR. O'CONNOR: Objection to form.</p> <p>22 A. That's correct.</p> <p>23 BY MS. HERZFELD:</p> <p>24 Q. So I guess my question is, if you had a</p>

<p style="text-align: right;">Page 322</p> <p>1 concern about a particular pharmacy -- for example, 2 because of an increased amount of sales -- and you 3 reached out to your distributor, your wholesaler 4 person, as you've said that you would, you would ask 5 them for an explanation? 6 A. That's right. 7 Q. And then they would come back to you with 8 an explanation? 9 A. That's correct. 10 Q. Would you do any additional investigation 11 to verify that the explanation they gave you was 12 accurate, or would you -- 13 A. No. 14 MR. O'CONNOR: Objection to form. 15 A. We worked with these distributors and 16 wholesalers, and I trusted what they were telling me. 17 BY MS. HERZFELD: 18 Q. Okay. That's my last question on this 19 document. 20 A. Okay. 21 MR. KO: Tricia, I hate to interrupt. Can 22 we go off the record for just one minute? 23 MS. HERZFELD: Sure. 24 THE VIDEOGRAPHER: We are going off the</p>	<p style="text-align: right;">Page 324</p> <p>1 Q. And other than what we've discussed with 2 your previous interaction with law enforcement in 3 Tennessee, are you aware of any other inquiries from 4 law enforcement in Tennessee about opioid abuse in 5 Tennessee? 6 A. Not that I can recall. 7 Q. And has Mallinckrodt communicated at all 8 with the Tennessee Attorney General about opioid abuse 9 or diversion in Tennessee? 10 A. I don't know about Tennessee. 11 Q. Do you know who the Attorney General of 12 Tennessee is right now? 13 A. I do not. 14 Q. Does the name Herb Slatery ring any bells 15 to you? 16 A. I'm sorry. It does not. 17 Q. What about a gentleman named Bob Cooper? 18 Kind of a general name, but Bob Cooper as the Tennessee 19 Attorney General, does that mean anything to you? 20 A. No. 21 Q. Have you personally communicated with 22 anyone at the Tennessee Attorney General's office about 23 the abuse or diversion of opioids in Tennessee? 24 A. No.</p>
<p style="text-align: right;">Page 323</p> <p>1 record at 5:47 PM. 2 [A brief recess was taken.] 3 THE VIDEOGRAPHER: We are back on the 4 record at 6:02 PM. 5 BY MS. HERZFELD: 6 Q. Okay, Mr. Gillies. We're back on the 7 record after a short break. I just have a few more 8 questions for you, and hopefully they'll be pretty 9 quick. 10 When you were talking earlier about the 11 role of wholesalers and distributors in the supply 12 chain and the policies that you have, along with those 13 for the distribution of opioids, are those different in 14 any way for Tennessee than they are nationally? 15 A. No. 16 MR. O'CONNOR: Objection to form. 17 BY MS. HERZFELD: 18 Q. Have you been involved -- strike that. 19 Have you -- are you aware of any formal or 20 informal investigations about opioid distribution 21 within Tennessee? 22 A. Outside what we've discussed? 23 Q. Yes, sir. 24 A. No.</p>	<p style="text-align: right;">Page 325</p> <p>1 Q. I think there was a topic about online 2 pharmacies. Do you know if any online pharmacies 3 shipped any Mallinckrodt products to Tennessee? 4 A. I'm not aware of any. 5 Q. Do you know if online pharmacies' ordering 6 of Mallinckrodt products had any connection to 7 Tennessee in any way? 8 MR. O'CONNOR: Objection to form. 9 A. I'm sorry. Could you restate that one 10 more time? Or repeat it, actually, not restate it. 11 BY MS. HERZFELD: 12 Q. Sure. Do you know if any online 13 pharmacies' ordering of Mallinckrodt products have any 14 connection to Tennessee? 15 A. I do not. 16 MR. O'CONNOR: Objection. 17 MS. HERZFELD: Okay. I don't have any 18 more questions for you. 19 A. Okay. 20 MS. HERZFELD: Thank you. 21 A. Thank you. 22 MR. O'CONNOR: Any questions from anybody 23 else? 24 MS. HARMON: No.</p>

<p style="text-align: right;">Page 326</p> <p>1 MR. O'CONNOR: I just have a very short, 2 very short list of questions. 3 MS. HERZFELD: Like your two minutes. 4 MR. O'CONNOR: Actually, it might be two 5 minutes. All right. 6 MR. GOLDSTEIN: It's attorney two minutes. 7 EXAMINATION 8 BY MR. O'CONNOR: 9 Q. Mr. Gillies, earlier today you provided 10 testimony in response to questions from Mr. Ko about 11 discussions with DEA concerning the abuse potential of 12 hydrocodone and hydromorphone; correct? 13 A. Yes. 14 Q. And you recall Mr. Ko's questions asked 15 about those two products together? 16 A. Yes. 17 Q. Are you aware of any discussions with the 18 DEA about the abuse potential of hydromorphone in 19 particular? 20 A. No. 21 Q. In preparing for today's deposition, you 22 reviewed materials related to Mallinckrodt's national 23 suspicious order monitoring program; correct? 24 A. Correct.</p>	<p style="text-align: right;">Page 328</p> <p>1 C E R T I F I C A T E 2 3 I, JOHN ARNDT, a Certified Shorthand 4 Reporter and Certified Court Reporter, do hereby 5 certify that prior to the commencement of the 6 examination, JOHN GILLIES was sworn by me to testify 7 the truth, the whole truth and nothing but the truth. 8 I DO FURTHER CERTIFY that the foregoing is a 9 true and accurate transcript of the proceedings as 10 taken stenographically by and before me at the time, 11 place and on the date hereinbefore set forth. 12 I DO FURTHER CERTIFY that I am neither a 13 relative nor employee nor attorney nor counsel of any 14 of the parties to this action, and that I am neither a 15 relative nor employee of such attorney or counsel, and 16 that I am not financially interested in this action. 17 18 19 20 _____ 21 JOHN ARNDT, CSR, CCR, RDR, CRR 22 CSR No. 084-004605 23 CCR No. 1186 24</p>
<p style="text-align: right;">Page 327</p> <p>1 Q. And you also reviewed materials relating 2 to other national efforts or national controls geared 3 towards the prevention of diversion? 4 A. Yes, our program is national. 5 Q. Does that suspicious order monitoring 6 program apply in the State of Tennessee? 7 A. It would. 8 Q. And do the other anti-diversion controls 9 you discussed today also apply in the State of 10 Tennessee? 11 A. Yes. 12 MR. O'CONNOR: All right. That's all I 13 have. 14 MS. HERZFELD: You're free to go. 15 MR. O'CONNOR: You want to go off the 16 record? 17 THE WITNESS: We're all free to go. 18 THE VIDEOGRAPHER: We are going off the 19 record at 6:07 PM. 20 21 [SIGNATURE RESERVED.] 22 23 24</p>	<p style="text-align: right;">Page 329</p> <p>1 2 I, JOHN GILLIES, the witness herein, 3 having read the foregoing testimony of the pages of 4 this deposition, do hereby certify it to be a true and 5 correct transcript, subject to the corrections, if any, 6 shown on the attached page. 7 8 9 10 11 _____ 12 JOHN GILLIES 13 14 Sworn and subscribed to before me, 15 This _____ day of _____, 201_. 16 17 18 _____ 19 Notary Public 20 21 22 23 24</p>

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